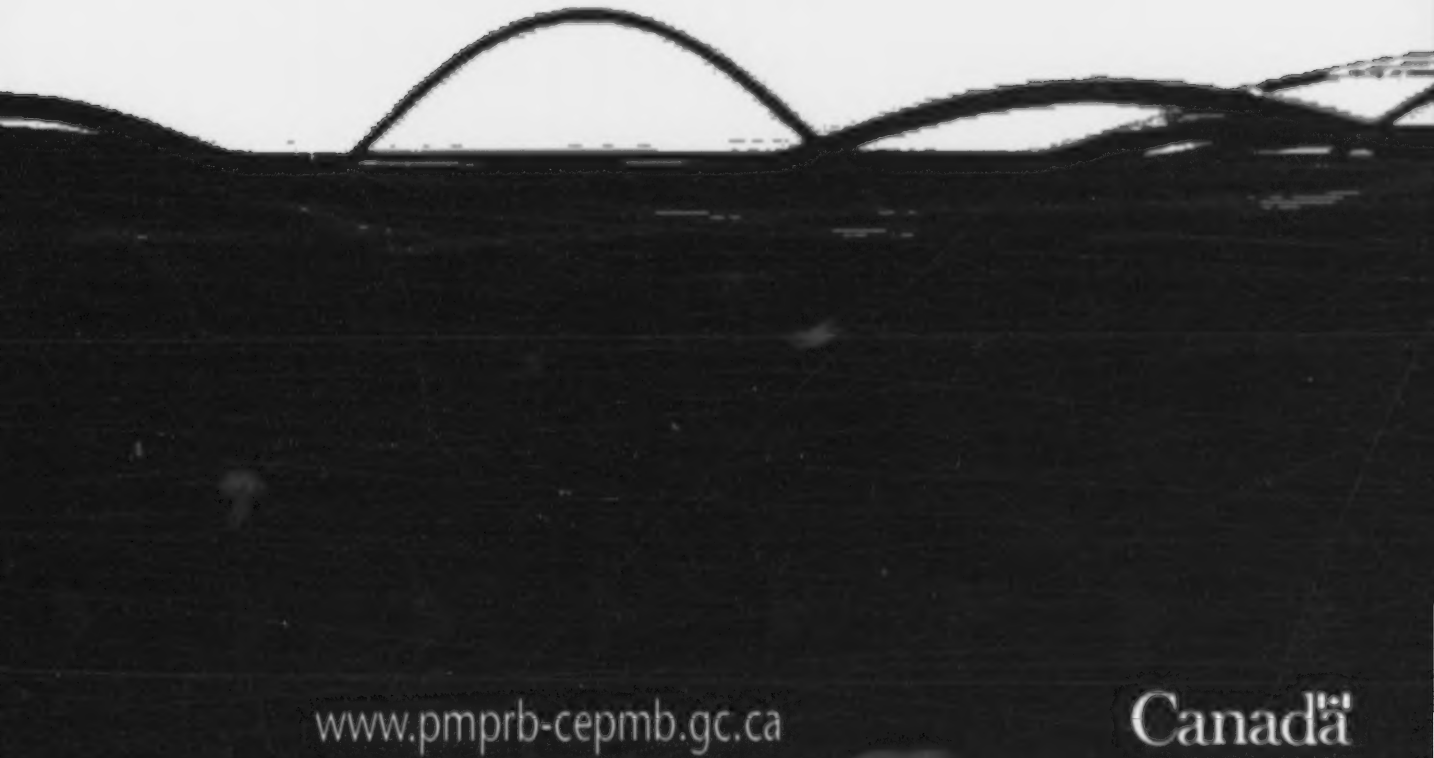
Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Patented Medicine Prices Review Board

Annual Report

2011



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Canada

The mandate of the Patented Medicine Prices Review Board is to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

Statistical Highlights 2011

Regulatory Mandate

Compliance

- 109 new patented drug products for human use reported to the PMPRB
  - 86 were within Guidelines
- In total, 1,282 patented drug products for human use were under the PMPRB's jurisdiction

Enforcement

Up to May 31, 2012:

- 15 Voluntary Compliance Undertakings accepted
- Three hearings completed: ratiopharm Inc.; ratio-Salbutamol HFA; and Copaxone Redetermination
- Decisions pending in two hearings: Sandoz Canada Inc.; and, Pentacel and Quadracel
- Two matters remain before the Board: Apotex Inc. and Apo-Salvent CFC Free

Reporting Mandate

Sales Trends

- Sales of patented drug products increased by 1.7% to $13.1B
- The share of patented drug products as a percentage of total sales rose slightly from 58.0% in 2010 to 59.1% in 2011
- Antineoplastics and immunomodulating agents made the largest positive contribution to sales growth while products related to the cardiovascular system had the largest decline

Patented Drug Price Trends

- Prices of patented drug products sold by patentees, as measured by the Patented Medicines Price Index, remained on average unchanged while the Consumer Price Index rose by 2.9%
- Canadian prices were the fourth highest among the seven comparator countries, lower than prices in Switzerland, Germany and the US.

Research and Development

- Patentees reported total R&D expenditures of $991.7 million, a decline of 15.8% over 2010
- Rx&D members reported $901.2 million in R&D expenditures, a 9.9% decline over 2010
- R&D-to-sales ratios declined in 2011:
  - all patentees, from 6.9% in 2010 to 5.6%
  - Rx&D members, from 8.2% to 6.7%

The Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Tel.: 613-952-7360
Fax: 613-952-7626
TTY 613-957-4373

Email: pmprb@pmprb-cepmb.gc.ca
Web: www.pmprb-cepmb.gc.ca
Twitter: @PMPRB_CEPMB

ISSN: 1495-8361
Catalogue number: H78-2011E-PDF

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Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

May 31, 2012

The Honourable Leona Aglukkaq, P.C., M.P.
Minister of Health
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Minister:

I have the pleasure to present to you, in accordance with sections 89 and 100 of the *Patent Act*, the Annual Report of the Patented Medicine Prices Review Board for the year ended December 31, 2011.

Yours very truly,

Mary Catherine Lindberg

Chairperson

Canada

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Chairperson's Message

This year the Patented Medicine Prices Review Board has focused on its commitment to fairness and transparency in carrying out its mandate.

We continue to assess our direction in light of ongoing shifts in the health care environment. Domestically and internationally, we continue to witness important changes as distribution practices evolve, sales models change, patentees introduce different types of benefit programs, and new types of drugs reach the market.

Our objective to ensure that Canadians do not pay excessive prices for patented medicines is an important one which contributes to protecting consumer interests and the health care system by impacting public and private payers and cash-paying customers. The decision issued by the Supreme Court of Canada on January 20, 2011, upholding key aspects of the Board's jurisdiction, provided an important clarification and affirmation of the PMPRB's consumer protection role.

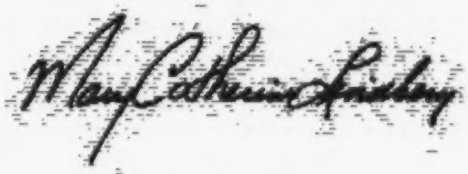
Our *Monitoring and Evaluation Plan for the Major Changes in the Guidelines* has proven to be an excellent platform for continued dialogue with patentees and stakeholders that enables us to be more responsive and allows for timely adjustments to our Guidelines. It is our intention that the Guidelines be responsive to changes in the drug distribution and pricing environment, in an appropriate timeframe.

To that end, among our priorities is to further enhance compliance by examining alternate dispute resolution models and to explore ways of decreasing the regulatory burden for patentees. Ongoing engagement with stakeholders will be crucial in meeting our long-standing commitment to a regulatory regime that is relevant, responsive and appropriate.

Of equal importance is the PMPRB's reporting role. Through the National Prescription Drug Utilization Information System (NPDUIS), we continue our partnership with the Canadian Institute for Health Information, Health Canada, and the provinces and territories. We provide policy makers and drug plan managers with information and insights on trends in prices, utilization and costs.

As Chairperson of the PMPRB it is my goal to ensure that our framework continues to have a positive impact for consumers while recognizing the value that innovative medicines offer to patients. To do so, I have had the pleasure of working with dedicated and knowledgeable colleagues on the Board and Staff. I would like to thank them for their commitment and continuous support. As Anne Warner La Forest's term ended in March, I would like to take this opportunity to thank her for her tremendous contribution to the Board and wish her success in her endeavours.

The PMPRB remains committed to effectively delivering its mandate of serving Canadians, and contributing to the health care system.



Mary Catherine Lindberg

About the Patented Medicine Prices Review Board

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act* (Act).

The PMPRB protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. It does this by reviewing the prices that patentees charge for each individual patented drug product in Canadian markets. If a price is found to be excessive, the Board can hold public hearings and order price reductions and/or the offset of excess revenues. The PMPRB regulates the "factory gate" prices and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees.

The PMPRB is also responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees.

Standing, from left to right: Anne Warner La Forest, Mitchell Levine, Tim Armstrong. Seated: Mary Catherine Lindberg.

The Minister of Health is responsible for the pharmaceutical provisions of the Act as set out in sections 79 to 103. The PMPRB is part of the Health Portfolio, which also includes Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research, the Hazardous Materials Information Review Commission, and Assisted Human Reproduction Canada.

The Health Portfolio supports the Minister of Health in maintaining and improving the health of Canadians.

Although part of the Health Portfolio, the PMPRB carries out its mandate at arm's length from the Minister of Health. It also operates independently of other bodies such as Health Canada, which approves drugs for safety, efficacy and quality; federal, provincial and territorial public drug plans, which are responsible for listing reimbursement decisions for their respective plans; and the Common Drug Review, which provides listing recommendations based on cost-effectiveness to participating public drug plans.

Jurisdiction

Regulatory

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada to ensure that they are not excessive. It includes sales to wholesalers, hospitals, pharmacies or others for both human and veterinary use. The PMPRB regulates the price of each patented drug product. This includes each strength of an individual, final dosage form of a medicine.

The Board's jurisdiction is not limited to drug products for which the patent is on the active ingredient. Rather, the Board's jurisdiction also covers drugs for which the patents relate to, but are not limited to, the processes of manufacture, the delivery system or dosage form, the indication/use and any formulations. Patented drug products are not limited to brand-name products.

A number of generic companies fall under the Board's jurisdiction by virtue of being licensees selling the same drug product as the brand company or because of manufacturing or processing patents, which various generic companies also hold.

The PMPRB has no authority to regulate the prices of non-patented drugs and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees. Also, matters such as whether medicines are reimbursed by public drug plans, their distribution and prescribing are outside the purview of the PMPRB.

Under the Act, patentees are required to inform the PMPRB of their intention to sell a new patented drug product. Upon the sale of such a patented drug product, patentees are required to file price and sales information at introduction and, thereafter, twice a year for each strength of each dosage form of each patented drug product sold in Canada.

Although patentees are not required to obtain approval of the price before a drug is sold, they are required to comply with the Act to ensure that prices of patented drug products sold in Canada are not excessive. In the event that the Board finds, after a public hearing, that a price is or was excessive in any market, it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received.

Reporting

The PMPRB reports annually to Parliament through the Minister of Health on its activities, on trends relating to the sales and prices of medicines, and on R&D spending by patentees.

Through the National Prescription Drug Utilization Information System (NPDUIS) program, the PMPRB provides critical analyses of price, utilization and cost trends in Canada to support decision making by participating federal, provincial and territorial public drug plans.

Governance

The Board consists of not more than five members who serve on a part-time basis. Board Members, including a Chairperson and a Vice-Chairperson, are appointed by the Governor-in-Council. The Chairperson is designated under the Act as the Chief Executive Officer of the PMPRB, with the authority and responsibility to supervise and direct its work.

The Members of the Board, including the Chairperson, are collectively responsible for the implementation of the applicable provisions of the Act. Together, they establish the guidelines, rules, by-laws and other policies of the Board as provided by the Act and consult as necessary with stakeholders including Ministers of Health and representatives of consumer groups, the pharmaceutical industry and others.

As of May 31, 2012, there were two vacancies on the Board.

Members of the Board

Chairperson
Mary Catherine Lindberg, BSP

Mary Catherine Lindberg was first appointed Member and Vice-Chairperson of the Board in June 2006. On May 19, 2010, Ms. Lindberg assumed the powers and functions of the Chairperson while the office was vacant. She was officially appointed Chairperson of the Board on March 3, 2011.

From 2002 to 2009, Ms. Lindberg was Executive Director of the Ontario Council of Academic Hospitals, an organization of 25 Academic Hospitals that are fully affiliated with a university and its Faculty of Medicine. Previously, she was the Assistant Deputy Minister, Health Services, with the Ontario Ministry

of Health and Long-Term Care. Her responsibilities included the Ontario Health Insurance Plan (OHIP) and the Ontario Drug Programs.

Ms. Lindberg has a degree in pharmacy from the University of Saskatchewan and holds a pharmacist license in both Saskatchewan and Ontario.

Vice-Chairperson
Mitchell Levine, BSc, MSc, MD, FRCPC, FISPE

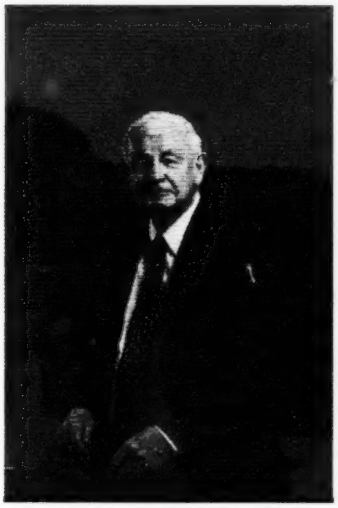
Dr. Mitchell Levine was appointed Member and Vice-Chairperson of the Board on March 3, 2011.

Dr. Levine is a professor in the departments of Clinical Epidemiology & Biostatistics and Medicine in the Faculty of Health Sciences at McMaster University in Hamilton, Ontario. He is also Director of the Centre for Evaluation of Medicines at St. Joseph's Healthcare in Hamilton.

Dr. Levine received his medical degree from the University of Calgary in 1979, which was followed by postgraduate training in Internal Medicine (FRCPC) and Clinical Pharmacology at the University of Toronto (1981–1987). He received an MSc degree in Clinical Epidemiology from McMaster University in 1988.

Prior to his appointment to the Board, Dr. Levine had been a member of the PMPRB's Human Drug Advisory Panel. He acts, on an ad hoc basis, as a clinical pharmacology consultant to the Ontario Ministry of Health and Long-Term Care. In addition, he is the Editor-in-Chief of the *Journal of Population Therapeutics and Clinical Pharmacology* and is an Associate Editor of the *ACP Journal Club: Evidence-Based Medicine.*

Thomas (Tim) Armstrong, QC, O. Ont.



Tim Armstrong was first appointed Member of the Board in October 2002 and was re-appointed for a second term in 2007.

Mr. Armstrong practiced law from 1958 to 1974, first in the Civil Litigation Division of the federal Department of Justice, subsequently in private practice in Toronto with Jolliffe, Lewis & Osler, and later as a senior partner of Armstrong & MacLean, specializing in administrative law litigation before administrative tribunals, the Ontario Courts, the Federal Court, and the Supreme Court of Canada.

In 1974, Mr. Armstrong became Chair of the Ontario Labour Relations Board (1974–1976), then Deputy Minister of Labour (1976–1986), Agent General for Ontario in Tokyo (1986–1990), Deputy Minister of Industry, Trade and Technology (1991–1992) and advisor to the Premier of Ontario on economic development (1992–1995). He was a facilitator/mediator for the Ontario Health Services Restructuring Commission (1998–1999) and the arbitrator under the *City of Toronto Labour Disputes Resolution Act* (2001). He was counsel to the law firm McCarthy Tétrault (1995–2002) and Chief Representative for Canada for the Japan Bank for International Cooperation (1996–2010). His 2010 report to the Ontario government on trades and apprenticeship led to the passage of legislation creating the Ontario College of Trades.

Mr. Armstrong currently serves as arbitrator and mediator by consensual, provincial and federal government appointment in the field of labour relations and is Chair of the Radiation Safety Institute of Canada and a member of the Ontario Press Council.

Mr. Armstrong received the Order of Ontario in 1995 in recognition of his contribution to public service in Ontario.

Anne Warner La Forest, LLB (UNB), LLM (Cantab)

Anne Warner La Forest was a Member of the Board from March 2007 until the completion of her term on March 4, 2012.

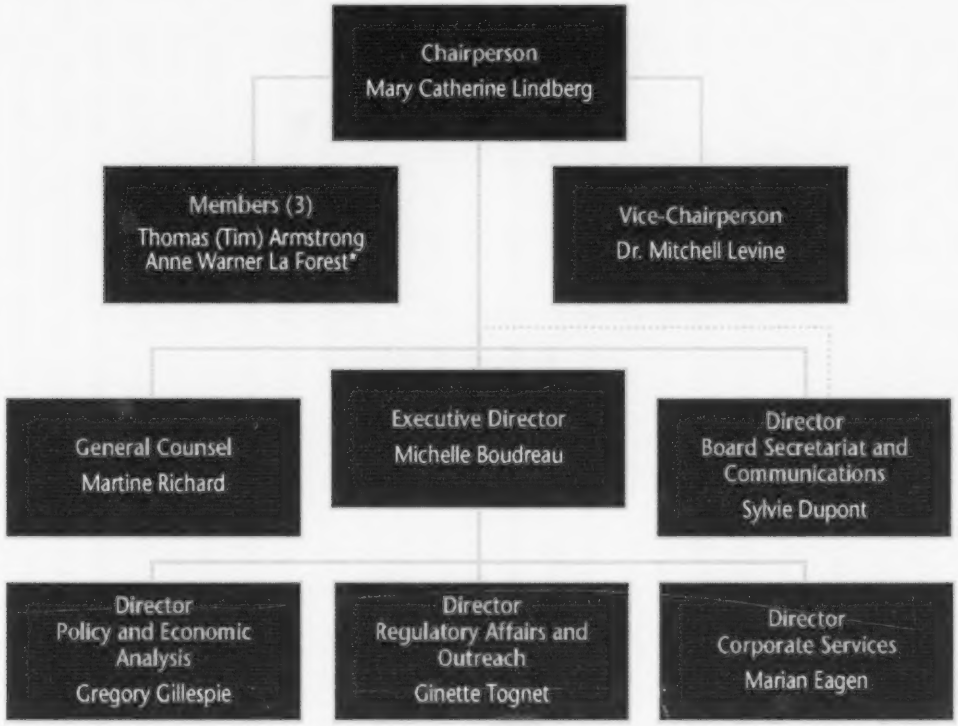
Ms. La Forest is currently a law professor at the University of New Brunswick. Member of the New Brunswick Securities Commission since 2004, she was also the Chair of the Commission's Human Resources Committee until June 2008 and was appointed Lead Member of the Commission in July of 2008.

After working in private practice with the firm of Fraser & Beatty in Toronto for several years, Ms. La Forest joined the Faculty of Law at Dalhousie University in 1991. In 1996, she was appointed Dean of the Faculty of Law of the University of New Brunswick, a position she held until 2004. A member of the bars of New Brunswick, Nova Scotia and Ontario, Ms. La Forest has extensive experience as an arbitrator and has acted as a consultant on matters relating to human rights, employment, property and extradition law. She has been a member of the Nova Scotia Human Rights Tribunal, a member of the Social Sciences and Humanities Research Council and Chair of the Fellowships Committee. She has also served as Arbitrator in the province of Nova Scotia, Commissioner of the province's Human Rights Commission and was a member of the Board of Governors of the National Judicial Institute. Ms. La Forest is a Fellow of the Cambridge Commonwealth Society.

She holds an LL.M. degree in International Law from Cambridge University in the United Kingdom.

Ms. La Forest has published many articles, books and case comments during her career and has been the chair or has served as a panelist at many national and international law conferences.

Organizational Structure and Staff



* Anne Warner La Forest completed her term as Board Member on March 4, 2012. As of this date, there were two vacancies on the Board.

Executive Director

The Executive Director is responsible for overall advice to the Board and for the leadership and management of the Staff.

Regulatory Affairs and Outreach

The Regulatory Affairs and Outreach Branch reviews the prices of patented drug products sold in Canada to ensure that they are not excessive; encourages patentees to comply voluntarily with the Board's Guidelines; implements related compliance policies; and investigates complaints into the prices of patented medicines. This Branch also informs and educates patentees on the Board's Guidelines and filing requirements.

Policy and Economic Analysis

The Policy and Economic Analysis Branch develops policy advice and recommendations on possible changes to the Board's Guidelines and on other policy issues, as required; conducts research and economic analysis on pharmaceutical trends and prepares reports; and conducts studies both in support of compliance and enforcement and as directed by the Minister of Health.

Corporate Services

The Corporate Services Branch provides advice and services in relation to human resources management, facilities, health, safety and security, information technology and information management. It is also responsible for strategic and financial planning and reporting, audit and evaluation, and liaison with federal central agencies on these topics.

Board Secretariat and Communications

The Board Secretariat and Communications Branch develops and manages the PMPRB's communications program, media relations and public enquiries; manages the Board's meeting and hearing processes, including the official record of proceedings; and coordinates activities pursuant to the *Access to Information Act* and the *Privacy Act*.

General Counsel

The General Counsel advises the PMPRB on legal matters and leads the prosecution team in proceedings before the Board.

Budget

The PMPRB operated with a budget of $11.8 million in 2011/12 and an approved staff level of 76 full-time equivalent employees.

TABLE 1 Budget and Staffing

	2010/11	2011/12	2012/13
Total PMPRB	$12,181 M	$11,832 M	$11,832 M
FTEs	76	76	76

Of the total budget in 2011/12, $3.1 million resided in a Special Purpose Allotment reserved strictly for external costs of public hearings (legal counsel, expert witnesses, etc.). Any unspent funds were returned to the Consolidated Revenue Fund.

Communications and Outreach

The Communications Program is responsible for planning and managing the PMPRB's external communications activities, as well as raising the organization's visibility and engaging with stakeholders. Information is exchanged in different forms, and through a variety of media, with consumers, provincial/territorial partners, industry and other stakeholders. Its main activities include, among others, media relations; responding to public inquiries; informing the public through publishing updates of Board proceedings and decisions and research results.

The Communications Group focuses on adapting to the changing requirements of the PMPRB's operating environment by evaluating its effectiveness and constantly exploring alternate communications products. In 2011, the PMPRB revamped its website and expanded its reach through the use of social media such as Twitter.

As a reliable, impartial source of comprehensive, accurate information on drug prices, the PMPRB is committed to developing and maintaining on-going collaboration with its stakeholders. In 2011, the PMPRB developed a plan to enhance non-industry stakeholder engagement. Through ongoing bilateral exchanges with federal/provincial/territorial health representatives, consumer representatives, patient-advocacy groups and others, the PMPRB aims at fostering greater awareness of its role to protect consumer interests and its contribution to Canadian health care.

Industry stakeholders are consulted and informed of changes in the operating environment and are promptly informed of any updates to the regulatory process. To facilitate patentees' access to information, the Regulatory Affairs and Outreach Branch conducts regular outreach sessions. With the recent revamping of the website, patentees benefit from improved access to information and documents pertinent to the industry. Webinars have also been introduced as a means of briefing patentees on the regulatory process.

Publications

In addition to regular publications including the *Annual Report* and the quarterly *NEWSletter*, the PMPRB publishes NPDUIS research reports in response to program and corporate requirements. In 2011, the PMPRB moved to electronic-only publication formats to reduce costs and decrease the environmental impact of printing.

The PMPRB remains committed to meeting its objectives with openness and transparency.

Patented
Medicine Prices
Review Board

Regulating Prices of Patented Medicines

Reporting Requirements

Patentees are required by law to file information pertaining to the sale of their drug products in Canada. The *Patent Act* (Act) along with the *Patented Medicines Regulations* (Regulations) set out the filing requirements, and Board Staff reviews the pricing information on an ongoing basis to ensure that the prices are not excessive. Patentees are required to file information with the PMPRB at introduction and then twice a year until the patent expires.

There are several factors used for determining whether a drug product is excessively priced, as outlined in section 85 of the Act. The *Compendium of Policies, Guidelines and Procedures* (Guidelines) details the various price tests used by Board Staff to determine whether a price charged by a patentee falls within the maximum allowable price. The Guidelines were developed in consultation with stakeholders including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. When an investigation determines that there is a problem with the price of a patented drug product, the patentee is offered the opportunity to voluntarily lower its price and/or refund its excess revenues through a Voluntary Compliance Undertaking (VCU). If the patentee disagrees with the results of the investigation and chooses not to submit a VCU, the Chairperson of the Board can issue a Notice of Hearing (NOH). A patentee may submit a VCU after the NOH has issued, or the matter may go to a public hearing. After hearing the evidence, if the Board finds that the price is indeed excessive, it can issue an Order to reduce the price and/or refund the excess revenues.

Copies of the Act, the Regulations, the Guidelines and the *Patentee's Guide to Reporting* are posted on the PMPRB's website.

Failure to Report

The PMPRB relies upon the patentees' full and timely disclosure of any and all drug products being sold in Canada to which a patent pertains. In 2011, 9 new drug products were reported to the PMPRB for the first time even though they were patented and sold prior to 2011.

Table 2 lists the drug products that were patented and sold in Canada prior to being reported to the PMPRB.

TABLE 2 Failure to Report the Sale of Patented Drugs

Currently sold by	Brand name	Generic name	Year medicine came under the PMPRB's jurisdiction
Abbott Laboratories Limited	Lupron Depot 3.75 mg/vial	Leuprolide acetate	1991
Abbott Laboratories Limited	Lupron Depot 7.5 mg/vial	Leuprolide acetate	1989
Baxter Corporation	Forane	Isolurane	2000
Baxter Corporation	Sevoflurane	Sevoflurane	2007
Biogen Idec Canada Inc.	Avonex PS 30 mcg/syringe	Interferon beta-1A	2005
GlaxoSmithKline	Fraxiparine 9500 unit/ml	Nadroparin calcium	2004
GlaxoSmithKline	Fraxiparine Forte 19000 unit/ml	Nadroparin calcium	2004
Grifols Canada Ltd.	Plasbumin-5 50 mg/ml	Albumin (human)	2006
Grifols Canada Ltd.	Plasbumin-25 250 mg/ml	Albumin (human)	2006

Failure to File Price and Sales Data (Form 2)

Failure to file refers to the complete or partial failure of a patentee to comply with the regulatory filing requirements outlined in the Act and the Regulations. There were no Board Orders issued for failure to file in 2011.

Scientific Review

Human Drug Advisory Panel

All new patented drug products reported to the PMPRB are subject to a scientific evaluation as part of the price review process. The Human Drug Advisory Panel (HDAP) was established by the Board to provide independent expertise and advice to Board Staff. HDAP reviews and evaluates scientific information available to the PMPRB respecting patented drug products, including any submission by a patentee with respect to the proposed level of therapeutic improvement, selection of drug products to be used for comparison purposes and comparable dosage regimens.

HDAP members base their recommendations on current medical and scientific knowledge and clinical practices. The members of HDAP are as follows:

- Dr. Jean Gray, Professor Emeritus of Medical Education, Medicine and Pharmacology at Dalhousie University
- Dr. Adil Virani, Director of Lower Mainland Pharmacy Services in Vancouver and Associate Professor in the Faculty of Pharmaceutical Sciences at the University of British Columbia
- Dr. Fred Y. Aoki, Professor of Medicine, Medical Microbiology and Pharmacology & Therapeutics, Faculty of Medicine, at the University of Manitoba
- Dr. Jacques LeLorier, Professor in the Departments of Medicine and Pharmacology at the University of Montreal
- Dr. Muhammad Mamdani, Director of the Applied Health Research Centre, Li Ka Shing Knowledge Institute at St. Michael's Hospital, Toronto and Associate Professor in the Department of Health Policy, Management and Evaluation (Faculty of Medicine) and the Leslie Dan Faculty of Pharmacy at the University of Toronto

Price Review

The PMPRB reviews the average price of each strength of an individual dosage form of each patented medicine. In most cases, this unit is consistent with the Drug Identification Number (DIN) assigned by Health Canada at the time the drug is approved for sale in Canada.

New Patented Drug Products Reported to the PMPRB in 2011

For the purpose of this report, a new patented drug product in 2011 is defined as any patented drug product first sold in Canada, or previously sold but first patented, between December 1, 2010, and November 30, 2011.

There were 109 new patented drug products for human use reported as sold in 2011. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of the 109 DINs for new patented drug products, 11 (10.1%) were being sold in Canada prior to the issuance of the Canadian patent that brought them under the PMPRB's jurisdiction. The table below shows the year of first sale for these DINs.

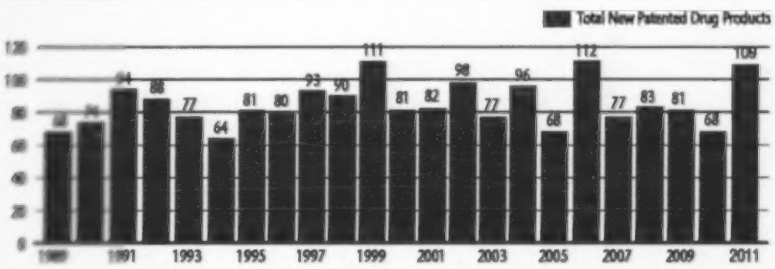
TABLE 3 Number of New Patented Drug Products for Human Use in 2011 by Year First Sold

Year First Sold	No. of DINs
2011	98
2010	6
2009	2
2008	1
2007	0
2006	1
2005	1
Total	109

The list of New Patented Medicines Reported to the PMPRB is available on the website under Regulating Prices. This list includes information on the status of the review (e.g., whether the medicine is under review, within the Guidelines, under investigation, or subject to a VCU or Notice of Hearing).

Figure 1 illustrates the number of new patented drug products for human use reported to the PMPRB from 1989 to 2011.

FIGURE 1 New Patented Drug Products for Human Use



Of the 109 new patented drug products

- the prices of 109 had been reviewed as of March 31, 2012:
  - 86 were found to be within the Guidelines
  - 10 were at levels that appeared to exceed the Guidelines by an amount which did not trigger the investigation criteria
  - 13 were priced at levels that appeared to exceed the Guidelines and investigations were commenced

A complete list of the 109 new patented drug products and their price review status appears in Appendix 2.

Price Review of Existing Patented Drug Products for Human Use in 2011

For the purpose of this report, existing patented drug products include all patented drug products that were first sold and reported to the PMPRB prior to December 1, 2010.

At the time of this report, there were 1,173 existing patented drug products:

- 993 were within the Guidelines
- 124 exceeded the Guidelines by an amount that did not trigger the investigation criteria
- 55 were the subject of investigations
  - 4 were opened as result of introductory pricing in 2010
  - 51 were opened on the basis of year-over-year prices
- 1 drug product was the subject of a price hearing under section 83 of the Act (see *Hearings*)
- 1 additional drug product remains the subject of a hearing although no longer patented in 2011

A summary of the status of the price review of the new and existing patented drug products for human use in 2011 is provided in Table 4.

TABLE 4 Patented Drug Products for Human Use Sold in 2011 – Status of Price Review as of March 31, 2012

	New drug products introduced in 2011	Existing drug products	Total
Total	109	1,173	1,282
Within Guidelines	86	993	1,079
Under Review	0	0	0
Does Not Trigger	10	124	134
Under Investigation	13	55	68
Price Hearings	—	1	1

Update from the 2010 Annual Report

- Reviews of all drug products for human use reported as Under Review in the 2010 Annual Report have been completed
- 65 of the 87 investigations reported in the 2010 Annual Report resulted in one of the following:
  - the closure of the investigation where it was concluded that the price was within the Guidelines
  - a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price and offset excess revenues through a payment and/or a reduction in the price of another patented drug product (see *Voluntary Compliance Undertakings*)
  - a public hearing to determine whether the price was excessive, including any remedial Order determined by the Board (see *Hearings*)

Patented Over-the-Counter Drug Products and Patented Drug Products for Veterinary Use

Board Staff will only review the price of a patented over-the-counter drug product or a patented veterinary drug product when a complaint has been received. No complaints were received in 2011.

Voluntary Compliance Undertakings and Hearings

Board Staff reviews the prices of all patented drug products sold in Canada. When it finds that the price of a patented drug product appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will conduct an investigation to determine if the price of the patented drug product in fact exceeds the Guidelines. An investigation could result in one of the following:

- its closure where it is concluded that the price was within the Guidelines
- a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price to a non-excessive level and offset excess revenues obtained as a result of an excessive price through a payment and/or an additional price reduction of the patented drug product or a price reduction of another patented drug product
- a recommendation from Board Staff to the Chairperson to issue a Notice of Hearing to hold a public hearing into the price of a patented medicine

Voluntary Compliance Undertakings

A VCU is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price set forth by the patentee for a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued.

In 2011, the Chairperson approved 9 VCUs. In the first quarter of 2012, the Chairperson approved 6 VCUs.

Patentees are to ensure that the prices of their patented drug products remain within the Board's Guidelines in all periods in which the drug products remain under the PMPRB's jurisdiction.

Hearings

In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing. If it finds that the price is excessive, it may issue an order to reduce the price and to offset revenues received as a result of the excessive price. Board decisions are subject to judicial review in the Federal Court of Canada.

TABLE 5 Voluntary Compliance Undertakings in 2011 up to May 31, 2012

Patented drug product	Therapeutic use	Patentee	Date of approval	Offset of excessive revenues	
				Price reduction	Payment to the Crown
VCUs in 2011					
Abilify	Schizophrenia	Bristol-Myers Squibb Canada Co.	Feb. 2011	$1,043,311	
Niaspan	Cholesterol	Sepracor Pharmaceuticals, Inc.	May 2011		$76,554
Suprane	Anesthetic	Baxter Corporation	April 2011		$43,659
Technescan MAG3	Renal imaging agent	Lantheus Medical	May 2011		$34,800
Sinemet CR	Parkinson's disease	Bristol-Myers Squibb Canada Co.	July 2011		$64,442
Effient	Antiplatelet	Eli Lilly Canada Inc.	Sept. 2011		$4,618
Nasonex	Allergic rhinitis	Merck Canada Inc.	Sept. 2011		$165,098
Orgalutran	Hormone (ovulation)	Merck Canada Inc.	Oct. 2011		$393,558.85
Trinipatch	Angina	Paladin Laboratories Inc.	June 2011		$92,266.70
VCUs in 2012, up to May 31					
Thalomid®	Multiple myeloma	Celgene Corporation	Jan. 2012		$10,000,000
Dovobet	Psoriasis	LEO Pharma Inc.	Jan. 2012		$32,019.98
Precedex	Sedation	Hospira Healthcare Corporation (Canada	Feb. 2012	$807,490	
Diflucan	Antifungal antibiotic	Pfizer Canada Inc.	May 2012		$30,951.51
Trileptal	Epilepsy	Novartis Pharmaceuticals Canada Inc.	May 2012		$1,000,000
Pariet	Gastric acid secretions	Janssen Inc.	May 2012		$217,413.07

In 2011, the Board issued decisions and/or orders effectively completing four matters: Sanofi-aventis Canada Inc., ratio-Salbutamol HFA and Copaxone (redetermination), on price; and ratiopharm Inc., on failure to file.

Decisions are pending in the matters of Sandoz Canada Inc., on failure to file, and Pentacel and Quadracel, on remedy.

Two proceedings are ongoing: Apotex Inc., on failure to file, and Apo-Salvent CFC Free, on price.

No new Notices of Hearing were issued in 2011.

Matters before the Federal Court

Three Board decisions are currently subject to judicial review by the Federal Court for the following: ratio-Salbutamol HFA; ratiopharm Inc. (now Teva Canada); and Copaxone Redetermination. Hearing dates have yet to be set in all three cases.

Matter before the Supreme Court of Canada

In January 2011, the Supreme Court dismissed the appeal by the Celgene Corporation, confirming the Board's jurisdiction over the price of Thalomid. The decision recognized that the purpose of the Board's legislative mandate is the protection of consumers.

Summary

In addition to price reductions, excess revenues totalling $24 million were offset by way of payments to the Government of Canada through VCUs and Board Orders in 2011 up to May 31, 2012.

Since 1993, the Chairperson has approved a total of 87 VCUs and initiated 25 public hearings. These measures resulted in price reductions and the offset of excess revenues by way of additional price reductions and/or payments to the Government of Canada and/or to customers such as hospitals and clinics. Approximately $123 million have been collected through VCUs and Board Orders by way of payments to the Government of Canada.

TABLE 6 Status of Board Proceedings in 2011 up to May 31, 2012

Patented drug product	Therapeutic use	Patentee	Issuance of Notice of Hearing	Status
Apo-Salvent CFC Free	Asthma	Apotex Inc.	July 8, 2008	Ongoing
Copaxone — Redetermination	Multiple sclerosis	Teva Neuroscience G.P.-S.E.N.C.	May 8, 2006 New panel struck Feb. 2010	Order: February 23, 2012 Payment of excess revenues: $2,801,285.00 Before the Federal Court
Penlac	Antifungal for nails	sanofi-aventis Canada Inc.	Mar 26, 2007	Order: January 31, 2011 Payment of excess revenues: $9,409,074.36
Pentacel and Quadracel	Immunization	sanofi pasteur Limited	Mar 27, 2007	Order: March 16, 2010 Federal Court decision issued July 12, 2011; matter (remedy) returned to Board Hearing Panel for reconsideration Decision pending
ratio-Salbutamol HFA	Asthma	ratiopharm Inc. (now Teva Canada)	July 18, 2008	Decision: May 27, 2011 Application for Judicial Review filed with the Federal Court June 27, 2011; hearing date to be announced

Patentee	Issue	Date of Notice of Application	Status
Apotex Inc.	Failure to file (jurisdiction)	March 3, 2008	Ongoing
Celgene Corporation	Failure to file (jurisdiction)	Board Decision January 21, 2008	Supreme Court of Canada decision issued January 20, 2011
ratiopharm Inc.	Failure to file (jurisdiction)	August 28, 2008	Order: June 30, 2011; amended: October 17, 2011 Application for Judicial Review filed with the Federal Court July 29, 2011; hearing date to be announced
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	Board Decision: Pending

Compendium of Policies, Guidelines and Procedures

The PMPRB is committed to making the price review process open and transparent to all stakeholders. The *Compendium of Policies, Guidelines and Procedures* (Guidelines) provides guidance to patentees and Board Staff on the application of factors set out in the *Patent Act* and the *Patented Medicines Regulations* to determine if the price of a patented drug product sold in Canada is excessive.

In 2005, the PMPRB initiated a review process to ensure that the Guidelines remained relevant, appropriate and effective in the modern pharmaceutical environment. This process included the publication of numerous discussion papers and an extensive series of consultations with all interested stakeholders. The PMPRB released new Guidelines in June 2009, which were implemented on January 1, 2010.[1]

Since implementation, the PMPRB has been monitoring and evaluating the application and impact of the changes to the Guidelines on an ongoing basis. In June 2011, the PMPRB published the *Monitoring and Evaluation Plan for the Major Changes to the Guidelines*.[2] The Board was presented with the first annual assessment under this Plan in December 2011, and a table summarizing results was published in January 2012.[3]

As patentees and Board Staff gain experience working with the new Guidelines, and as monitoring and evaluation proceeds, new issues will continue to be identified. Clarifications are promptly communicated through the quarterly *NEWSletter*, and stakeholders are consulted on proposed amendments to the Guidelines through the Notice and Comment process. A revised version of the Guidelines, reflecting all changes is released annually in June.

1 The *Compendium of Policies, Guidelines and Procedures* is available on the PMPRB website under Legislation, Regulations and Guidelines.

2 The *Monitoring and Evaluation Plan for the Major Changes to the Guidelines* is available on the PMPRB website under Legislation, Regulations and Guidelines.

3 The table has been incorporated into the *Monitoring and Evaluation Plan for the Major Changes to the Guidelines*.

Patented
Medicine Prices
Review Board

Key Pharmaceutical Trends

Trends in Sales of Patented Drug Products

Patentees are required under the *Patented Medicines Regulations* (Regulations) to submit detailed information on their sales of patented drug products, including quantities sold and sales received for each product by class of customer in each province/territory. The PMPRB uses this information to analyze trends in sales, prices and utilization of patented drug products.[4] This section provides key statistical results from this analysis.

Sales and Prices

Canadians spend much more today on patented drug products than they did a decade ago, but it is important to understand that an increase in drug spending does not in itself imply rising drug prices. The PMPRB's Annual Reports from 1995 through 2003 noted that sales of patented drug products grew at annual rates consistently exceeding 10%, while average annual rates of change for prices were less than 1%. In these instances, sales growth was driven by changes in the volume and composition of drug utilization.

A variety of factors can produce such changes. These include:

- increases in total population
- changes in the demographic composition of the population (for example, shifts in the age distribution toward older persons with more health problems)
- increases in the incidence of health problems requiring drug therapy
- changes in the prescribing practices of physicians (for example, shifts away from older, less expensive drug products to newer, more expensive medications, or a shift toward higher, more frequent dosages)
- increases in the use of drug therapy instead of other forms of treatment
- the use of new drug products to treat conditions for which no effective treatment existed previously

Sales Trends

Table 7 reports patentees' total sales of patented drug products in Canada for 1990 through 2011. In 2011, sales of patented drug products increased to $13.1 billion from $12.9 billion in 2010, an increase of 1.7%. By comparison, the annual growth in sales stood at 27.0% in 1999 and remained in double-digits until 2003.

The third column of Table 7 gives sales of patented drug products as a share of overall drug sales. This share rose from 43.2% in 1990 to a peak of 72.7% in 2003. It has generally declined since 2003, implying that sales of non-patented brand and generic drug products have grown faster than sales of patented drug products in recent years.

TABLE 7 Sales of Patented Drug Products, 1990–2011

Year	Patented drug products		Sales of patented drug product share of all drug sales (%)*
	Sales ($billions)	Change (%)	
2011	13.1	1.7	59.1
2010	12.9	-3.4	58.0
2009	13.3	3.3	65.5
2008	12.9	5.0	64.7
2007	12.3	3.4	63.2
2006	11.9	3.5	67.8
2005	11.5	4.5	70.6
2004	11.0	7.8	72.2
2003	10.2	14.3	72.7
2002	8.9	17.5	67.4
2001	7.6	18.9	65.0
2000	6.3	16.7	63.0
1999	5.4	27.0	61.0
1998	4.3	18.9	55.1
1997	3.7	22.6	52.3
1996	3.0	12.8	45.0
1995	2.6	10.8	43.9
1994	2.4	-2.1	40.7
1993	2.4	9.4	44.4
1992	2.2	14.0	43.8
1991	2.0	13.1	43.2
1990	1.7	—	43.2

* The denominator in this ratio comprises sales of patented, non-patented brand and generic drug products. Starting with the estimate for 2005, this value is derived from data contained in IMS Health's MIDAS database. In previous years, IMS data were used to calculate sales of generic drug products only, while sales of non-patented brand products were estimated from data submitted by patentees. This approach was abandoned because of anomalies related to year-to-year changes in the set of companies reporting to the PMPRB. Ratios reported for years before 2005 likely overstate the patented share, but by only a small amount. This small bias in no way invalidates the strong upward trend evinced by the results for the years 1990 through 2003.

Sources: PMPRB and MIDASQ, 2005–2011, IMS Health Incorporated or its affiliates. All rights reserved.[5]

Drivers of Sales Growth

Table 8 decomposes the sales growth that occurred between 2010 and 2011 into distinct elements reflecting the impacts of:

- previously patented drug products that have gone off-patent or left the Canadian market ("exiting drug effect")
- patented drug products introduced to the Canadian market in 2011 ("new drug effect")
- changes in prices among patented drug products with sales in Canada in both 2010 and 2011 ("price effect")
- differences in the quantities of such drug products sold in the two years ("volume effect")
- interactions of price and quantity changes ("cross effect")

The first row of Table 8 gives these impacts as dollar amounts. The second row expresses the impacts as proportions of the overall change in sales between 2010 and 2011. For the sake of comparison, the third row provides average year-over-year proportionate impacts for 2006 through 2010.[6]

The results in this table show that the increase in sales that occurred between 2010 and 2011 was the result of increases in the quantity of the new and existing drug products sold; all other components contributed negatively toward the overall increase in sales. In particular, drug products going off-patent (exiting drug effect) and price decreases among existing patented drug products both had a negative impact on the increase in sales.

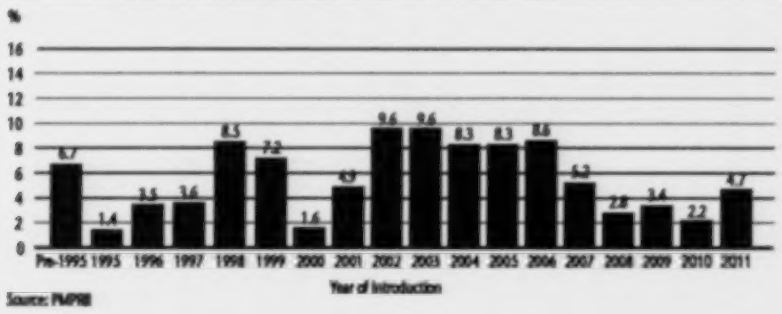
The pronounced decline in rates of sales growth over the last few years is a striking development. Figure 2 breaks down 2011 sales of patented drug products according to the year in which the product was first sold in Canada. Throughout the latter part of the 1990s and early 2000s, sales growth was largely driven by a succession of new "blockbuster" products that ultimately achieved very high sales volumes: despite the recent patent expiries, these products still accounted for a substantial share of sales in 2011. Since the beginning of the 2000s, high-volume products have not been introduced in sufficient numbers to sustain the double-digit sales growth seen in the previous decade.

TABLE 8 Decomposition of Changes in Sales of Patented Drug Products

	Total change	Exiting drug effect	New drug effect	Price effect	Volume effect	Cross effect
Sales impact, 2011/2010 ($millions)	219.7	-196.6	385.7	-20.0	53.8	-2.0
Proportion of total change, 2011/2010 (%)	100.0	-89.5	175.5	-9.1	24.5	-0.9
Average proportion of total change, 2006-2010 (%)	100.0	-49.7	62.9	-0.9	87.2	0.6

Source: PMPRB

FIGURE 2 Share of 2011 Sales of Patented Drug Products by Year of Introduction



Source: PMPRB

Sales by Therapeutic Class

The PMPRB classifies drug products according to the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) system when it conducts analyses at the level of therapeutic class. This is a hierarchical system that classifies drug products according to their principal therapeutic use and chemical composition. At its first level of aggregation (Level 1), the ATC system classifies drug products according to the element of human anatomy with which they are primarily associated.

Table 9 breaks out sales of patented drug products in Canada in 2011 by major therapeutic class, defined by ATC Level 1. The table gives the 2011 sales for each class, the share of the total sales this represents and the rate at which sales grew relative to 2010. Values in the last column represent the component of overall sales growth attributable to drug products in the corresponding therapeutic class.[7] By this measure, antineoplastics and immunomodulating agents made the largest positive contribution to sales growth. This contribution was more than offset by the declining sales of patented drug products related to the cardiovascular system and, secondarily, the musculo-skeletal system classes.

TABLE 9 Sales of Patented Drug Products by Major Therapeutic Class, 2011

Therapeutic class	2011 sales ($millions)	Share: 2011 sales (%)	Growth: 2011/2010 ($millions)	Growth: 2011/2010 (%)	Impact on change in expenditure (%)
A: Alimentary tract and metabolism	1,115.2	8.5	92.4	9.0	41.9
B: Blood and blood forming organs	951.5	7.2	74.9	8.5	34.0
C: Cardiovascular system	2,025.2	15.4	-573.1	-22.1	-260.1
D: Dermatologicals	90.2	0.7	6.4	7.6	2.9
G: Genito-urinary system and sex hormones	549.1	4.2	4.6	0.8	2.1
H: Systemic hormonal preparations	73.5	0.6	-33.5	-31.3	-15.2
J: General antiinfectives for systemic use; and P: Antiparasitic products*	1,368.9	10.4	72.5	5.6	32.9
L: Antineoplastics and immunomodulating agents	3,067.5	23.3	381.5	14.2	173.1
M: Musculo-skeletal system	432.0	3.3	-43.7	-9.2	-19.8
N: Nervous system	1,807.4	13.7	121.2	7.2	55.0
R: Respiratory system	1,163.8	8.8	49.0	4.4	22.2
S: Sensory organs	447.8	3.4	65.4	17.1	29.7
V: Various	59.9	0.5	2.8	4.9	1.3
All therapeutic classes	13,151.8	100.0	220.4	1.7	100.0

* These groups have been combined for reasons of confidentiality.

Source: PMPRB

4 All statistical results for patented drug products reported in this chapter are based on data submitted by patentees as of April 2012. On occasion, patentees report revisions to previously submitted data or provide data not previously submitted. New data of this sort can appreciably affect the statistics in this chapter. To account for this possibility, the PMPRB has adopted the practice of reporting recalculated sales figures (see *Trends in Sales of Patented Drug Products*), price and quantity indices (see *Price Trends* and *Utilization of Patented Drug Products*) and foreign-to-Canadian price ratios (see *Comparison of Canadian Prices to Foreign Prices*) for the five years preceding the current Annual Report year. All such recalculated values reflect currently available data. Consequently, where data revisions have occurred, values reported here may differ from those presented in earlier Annual Reports.

5 Although based in part on data obtained under license from the MIDAS IMS database, the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IMS AG.

6 Under the scheme applied here, the "exiting drug effect" is the amount of 2011 sales generated by drug products that were under the PMPRB's jurisdiction in 2010 but not in 2011. The "new drug effect" is the amount of 2011 sales generated by drug products that were under the PMPRB's jurisdiction in 2011 but not in 2010. Other effects are derived by means of the relationship:

$$\Sigma\, p^{2011}(i)\, q^{2011}(i) - \Sigma\, p^{2010}(i)\, q^{2010}(i) = \Sigma\, [p^{2011}(i) - p^{2010}(i)] q^{2010}(i) + \Sigma\, p^{2010}(i)\, [q^{2011}(i) - q^{2010}(i)] + \Sigma\, [p^{2011}(i) - p^{2010}(i)]\, [q^{2011}(i) - q^{2010}(i)]$$

where $p^y(i)$ is the price of drug i in year y, $q^y(i)$ is the physical volume of drug i sold in year y and Σ signifies summation over the set of drug products that were under the PMPRB's jurisdiction in both 2010 and 2011. The left-hand-side of this equation represents the change in total sales of such products between 2010 and 2011. The three terms of the right-hand-side define the volume, price and cross effects, respectively, reported in Table 8.

7 This is obtained as the ratio of the year-over-year change in the dollar value of sales for the therapeutic class in question to the change in sales across all patented drug products.

Price Trends

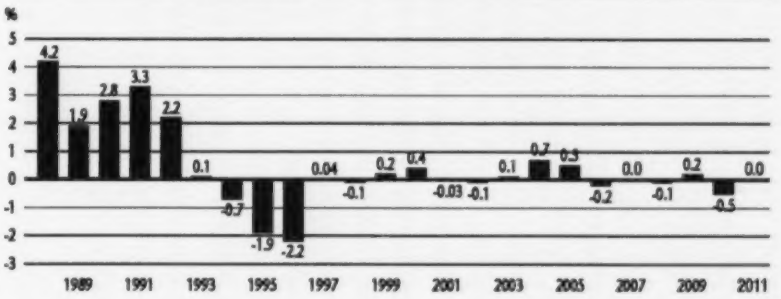
The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in prices of patented drug products. The PMPI measures the average year-over-year change in the ex-factory prices of patented drug products sold in Canada. The index is constructed using a formula that takes a sales-weighted average of price changes observed at the level of individual drug products.[8] This is similar to the approach Statistics Canada uses to construct the Consumer Price Index (CPI). The PMPI is updated every six months using price and sales information submitted by patentees.

It is important to understand the conceptual relationship between the PMPI and drug costs. The PMPI does not measure changes in the utilization of patented drug products; a quantity index, the PMQI, is calculated for this purpose (see *Utilization of Patented Drug Products*). The PMPI does not measure the cost impact of changes in prescribing patterns or the introduction of new medicines. By design, the PMPI isolates the component of sales growth attributable to changes in prices.

Figure 3 provides year-over-year changes in the PMPI for the years 1988 through 2011. As measured by the PMPI, prices of patented drug products have, on average, remained unchanged (0.0%) between 2010 and 2011.

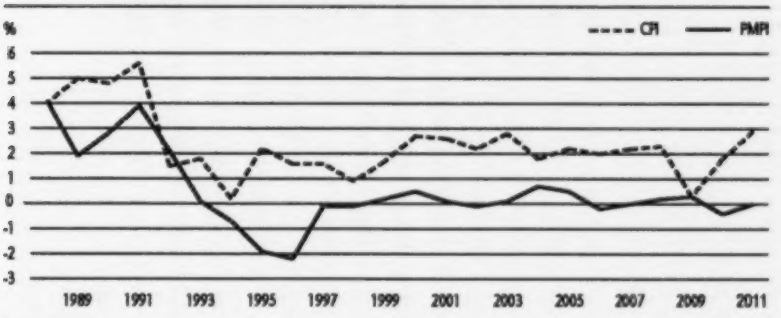
The *Patent Act* requires the PMPRB to consider changes in the Consumer Price Index (CPI), among other factors, in determining whether the price of a patented drug product is excessive. Figure 4 plots year-over-year rates of change in the PMPI against corresponding changes in the CPI. General price inflation, as measured by the CPI, has exceeded the average increase in patented drug prices almost every year since 1988. In 2011, the CPI rose by 2.9%, while the PMPI on average recorded no price change.

FIGURE 3 Annual Rates of Price Change, Patented Medicines Price Index (PMPI), 1988–2011



Source: PMPRB

FIGURE 4 Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 1988–2011



Source: PMPRB

It is not surprising that the PMPI has seldom kept pace with the CPI. The PMPRB's Guidelines allow the price of a patented drug product to rise by no more than the CPI over any three-year period. (The Guidelines also impose a cap on year-over-year price increases equal to one-and-one-half times the current year rate of CPI inflation.) This effectively establishes CPI inflation as an upper bound on the amount by which individual prices may rise over any period of three years.[9] Increases in the PMPI normally do not reach this upper bound because some patentees do not raise their prices by the full amount permitted under the Guidelines, or choose to reduce their prices.

Price Change by Therapeutic Class

Table 10 provides average rates of price change among patented drug products at the level of major therapeutic classes. Results in this table were obtained by applying the PMPI methodology to data segregated by their ATC Level I class. The last column provides a decomposition of overall PMPI change, with each entry representing the component of the overall change attributable to drug products in the corresponding therapeutic class. By this measure, no change in PMPI (0.0%) reflects a general state of price stability across therapeutic classes. Note all the therapeutic classes saw an average rate of price change below the rate of CPI inflation.[10]

TABLE 10 Change in the Price, Patented Medicines Price Index (PMPI), by Major Therapeutic Class, 2011

Therapeutic class	Share: 2011 sales (%)	Price change: 2010 to 2011 (%)	Contribution to the PMPI (%)
A: Alimentary tract and metabolism	8.5	-1.6	-0.1
B: Blood and blood forming organs	7.2	1.0	0.1
C: Cardiovascular system	15.4	0.1	0.0
D: Dermatologicals	0.7	0.7	0.0
G: Genito-urinary system and sex hormones	4.2	0.4	0.0
H: Systemic hormonal preparations	0.6	0.4	0.0
J: General Antiinfectives for systemic use; and P: Antiparasitic products*	10.4	-0.1	0.0
L: Antineoplastics and immunomodulating agents	23.3	-0.2	0.0
M: Musculo-skeletal system	3.3	0.5	0.0
N: Nervous system	13.7	0.6	0.1
R: Respiratory system	8.8	0.1	0.0
S: Sensory organs	3.4	0.2	0.0
V: Various	0.5	-2.5	0.0
All therapeutic classes	**100.0**	**0.0**	**0.0**

* These groups have been combined for reasons of confidentiality.

Source: PMPRB

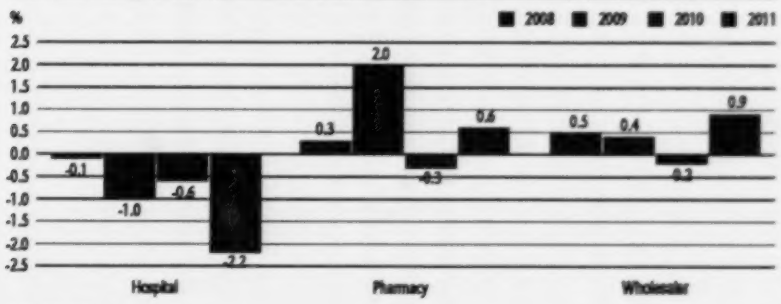
Price Change by Class of Customer

Figure 5 presents average rates of price change by class of customer.[11] These results were obtained by applying the PMPI methodology separately to sales data for hospital, pharmacy and wholesale customers.[12] The 2011 rates of price change for these classes were, respectively, -2.2%, 0.6% and 0.9%.

Price Change by Province/Territory

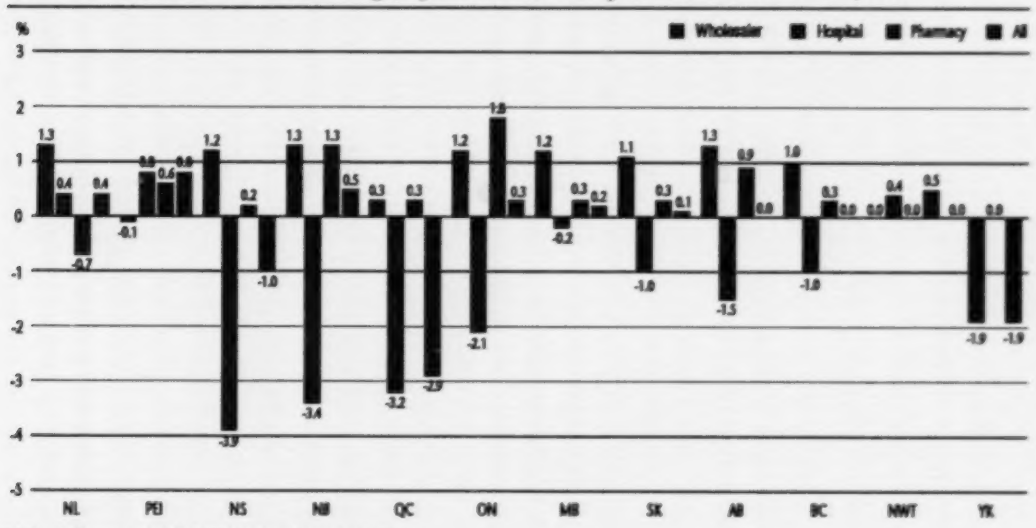
Figure 6 presents average annual rates of price change by province/territory, obtained by applying the PMPI methodology to sales data segregated by the province/territory in which the sale occurred. These results indicate that, between 2010 and 2011, prices of patented drug products in Nova Scotia, Quebec, and the Yukon fell on average.

FIGURE 5 Annual Rate of Price Change, Patented Medicines Price Index (PMPI), by Class of Customer, 2008–2011



Source: PMPRB

FIGURE 6 Annual Rate of Price Change, by Province/Territory* and Class of Customer, 2011



* Values for Nunavut are included in the Northwest Territories (NWT).

Source: PMPRB

Price Behaviour After Introduction

Does the price of a typical patented drug product change much in the years after it enters the Canadian market? To answer this question, Figure 7 provides the average ratio of the 2011 price to introductory price (the price at which the drug product was sold in its first year on the Canadian market).

The results in Figure 7 imply no consistent tendency for prices to either rise or fall after introduction, with the 2011 price of a typical patented drug product being within a few percentage points of its introductory price, regardless of when it was introduced to the Canadian market.[13]

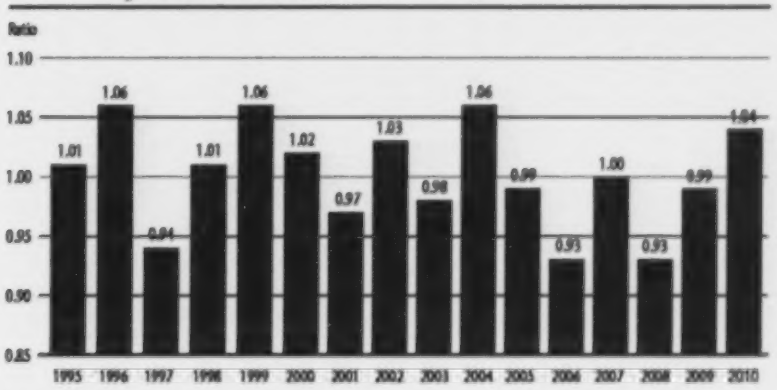
Price Change by Country

In accordance with the Act and the Regulations, patentees must report publicly available prices of patented drug products for seven foreign comparator countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

The PMPRB uses this information to

- conduct the international price comparison tests specified in its Guidelines
- compare Canadian prices of patented drug products to those prevailing in other countries

FIGURE 7 Average Ratio of 2011 Price to Introductory Price, by Year of Introduction

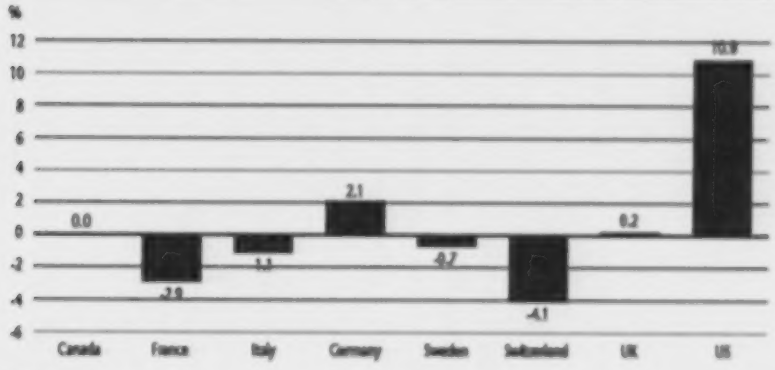


Source: PMPRB

Figure 8 gives the average annual rates of price change for Canada and each of the seven comparator countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to the international price data that patentees have submitted to the PMPRB. Note that results for the United States are based on prices that incorporate prices from the US Federal Supply Schedule (FSS).[14]

The results in Figure 8 indicate that in 2011, the United States saw prices rise on average at a rate of 10.9%. Germany and the United Kingdom saw much more modest average price increases, while prices in France, Italy, Switzerland and Sweden declined.

FIGURE 8 Annual Average Rates of Price Change, Canada and Comparator Countries, 2011



Source: PMPRB

8 These calculations are performed at the level defined by Health Canada's Drug Identification Number (DIN). Each DIN represents a unique combination of active ingredient(s), dosage form, strength(s), brand and manufacturer.

9 It is possible for individual prices (or, for that matter, the PMPI) to rise by more than the CPI in a given year. This can occur when patentees have banked price adjustments in the preceding years. It can also occur when the forecast rate of CPI inflation exceeds the actual rate. To allow patentees to set prices in advance, the CPI-Adjustment Methodology provides for the calculation of the CPI-adjustment factors based on forecast changes in the CPI. This raises the possibility of price increases exceeding CPI inflation wherever forecast CPI inflation exceeds actual CPI inflation. Note that this will not be a permanent gain as the patentee is expected to comply with the actual CPI in all subsequent reporting periods.

10 Suppose R represents the overall rate of change in the PMPI. Suppose there are N therapeutic classes, indexed by 1, 2 ... N. Let $R(I)$ represent the average rate of price change in major therapeutic class I obtained by means of the PMPI methodology. Using the fact that R is a sales-weighted average of price changes taken over all patented drug products, it is easy to derive the following relationship:

$R = w(1) \times R(1) + w(2) \times R(2) + \ldots + w(N) \times R(N)$,

where $w(I)$ represents the share of therapeutic class I in the sales of patented drug products. This relationship provides the basis for the decomposition in the last column of Table 10. Each term on its right-hand-side multiplies the average rate of price change for a given therapeutic class by its share of overall sales. The resulting value is readily interpreted as the contribution of the corresponding class to the change in the overall PMPI. Note that the size of this contribution depends on both the rate of price change specific to the class and its relative importance, as measured by its share of sales.

The decomposition in Table 10 is approximate. This is because the weights used to calculate the contribution of each therapeutic class are based on annual sales data, whereas rates of price change (whether overall or by therapeutic class) are calculated from data covering six-month reporting periods. The resulting discrepancy is normally small.

11 Sales of patented drug products are dominated by sales to wholesalers, which accounted for 79.8% of all sales in 2011. Sales to hospitals accounted for another 8.6%, while direct sales to pharmacies accounted for 4.6%. The pharmacy share has fallen precipitously since 2001, when it stood at 20.1%.

12 Results for a fourth class of customer, "Others", are not provided. This class accounted for about 7.0% of patented drug sales in 2011. Buyers in this class are principally health care institutions other than hospitals, such as clinics and nursing homes. It also includes direct sales to governments. The composition of this class is thought to vary substantially from one year to the next, rendering any analysis of price change in this class of limited value.

13 It must be emphasized that this statement refers to the behaviour of prices on average. There are undoubtedly instances where individual prices have risen or fallen substantially since introduction.

14 The pharmaceutical industry in the US has argued that the publicly available prices in that country do not reflect actual prices because of confidential discounts and rebates. Effective January 2000, and following public consultation, the PMPRB began including prices listed in the US Federal Supply Schedule (FSS) in calculating the average US price of patented drug products. The FSS prices are negotiated between manufacturers and the US Department of Veterans' Affairs. They are typically less than other publicly available US prices reported to the PMPRB by patentees.

Comparison of Canadian Prices to Foreign Prices

Tables 11 and 12 provide detailed statistics comparing the foreign prices of patented drug products to their Canadian prices. Each table provides two sets of average price ratios. These are differentiated according to the method by which foreign prices were converted to their Canadian dollar equivalents. The tables also give the numbers of drug products (DINs) and the volume of sales encompassed by each reported price ratio.[15]

The average price ratios given in Tables 11 and 12 are sales-weighted arithmetic means of price ratios obtained for individual drug products, with weights based on Canadian sales patterns. Average price ratios constructed in this way provide exact answers to questions of the type:

How much more/less would Canadians have paid for the patented drug products they purchased in 2011 had they paid Country X prices rather than Canadian prices?

For example, Table 11 states that the 2011 average French-to-Canadian price ratio was 0.84. This means Canadians would have paid 16% less for the patented drug products they purchased in 2011 had they bought these products at French prices.

For many years, the PMPRB has reported average foreign-to-Canadian price ratios with foreign prices converted to their Canadian dollar equivalents by means of market exchange rates. (More exactly, the 36-month moving averages of market rates the PMPRB normally uses in applying its Guidelines.) Table 11 also reports foreign-to-Canadian price ratios with currency conversion at purchasing power parity (PPP). The PPP between any two countries measures their relative costs of living expressed in units of their own currencies. In practice, cost of living is determined by pricing out a standard "basket" of goods and services at the prices prevailing in each country. Because PPPs are designed to represent relative costs of living, they offer a simple way to account for differences in overall national price levels when comparing individual prices, incomes and other monetary values across countries. When applied to the calculation of average foreign-to-Canadian price ratios they produce statistics answering questions of the type:

How much more/less consumption of other goods and services would Canadians have sacrificed for the patented drug products they purchased in 2011 had they lived in Country X?

Questions of this type cannot be answered by simply comparing drug prices. Rather, one must first calculate what each price represents in terms of goods and services foregone. PPPs are designed for such purposes.

Bilateral Price Comparisons

Table 11 provides bilateral comparisons of prices in each of the PMPRB's seven comparator countries to corresponding Canadian prices. Focusing on the results with currency conversion at market exchange rates, it appears that, as in previous years, Canadian prices were typically within the range of prices observed among the comparator countries. Canadian prices were roughly in line with Swedish and Swiss prices. Prices in France, Italy and the United Kingdom were appreciably lower than Canadian prices, while those in Germany were substantially higher. As in previous years, prices reported for the United States were much higher than prices in Canada or any other comparator country.

TABLE 11 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2011

	Canada	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
At Market Exchange Rates								
Average price ratio 2011	1.00	0.84	0.84	1.20	0.95	1.03	0.82	1.98
Average price ratio 2010	1.00	0.90	0.87	1.20	0.98	1.03	0.86	1.91
At Purchasing Power Parities								
Average price ratio 2011	1.00	0.81	0.89	1.27	0.88	0.81	0.91	2.28
Average price ratio 2010	1.00	0.85	0.88	1.22	0.91	0.80	0.90	2.31
Number of patented drug products	1,244	719	821	880	875	811	863	1,054
Sales ($millions)	13,151.8	10,827.9	11,149.3	11,460.0	11,458.9	11,270.2	11,351.2	12,361.4

Source: PMPRB

Average price ratios obtained with currency conversion at PPPs tell a somewhat different story. When international differences in cost of living are accounted for, it appears Canadians incurred a substantially larger consumption cost for the patented drug products they purchased in 2011 than did residents of every other comparator country except Germany and the United States.

Figure 9 puts these results in historical perspective. In 2005, Canadian prices were, on average, approximately equal to or below corresponding prices in all comparators other than Italy. By 2011, Canadian prices were decidedly above prices in the United Kingdom, France, and Italy and somewhat higher than prices in Sweden.

Multilateral Price Comparisons

Table 12 provides average foreign-to-Canadian price ratios using several multilateral measures of foreign prices. The median international price (MIP) is the median of prices observed among the seven comparator countries. Other multilateral price ratios compare the minimum, maximum and simple mean of foreign prices to their Canadian counterparts.

FIGURE 9 Average Foreign-to-Canadian Price Ratios: 2005, 2011

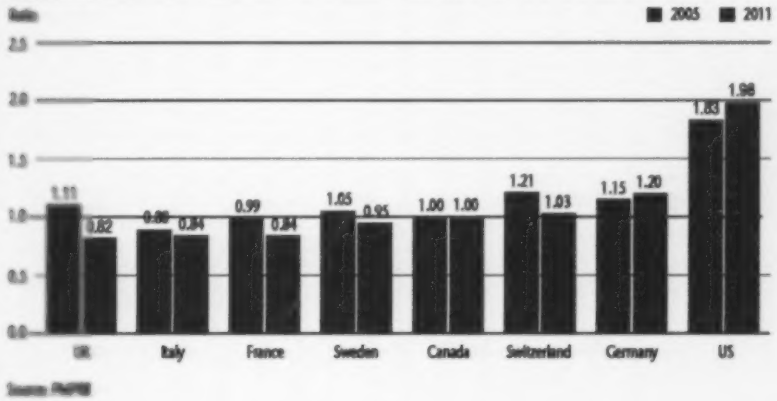


TABLE 12 Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2011

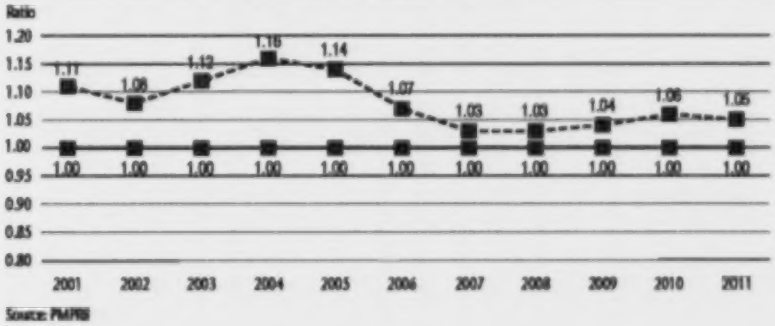
	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	1.05	0.79	2.08	1.18
Average price ratio at purchasing power parities	1.02	0.81	2.34	1.22
Number of patented drug products	1,175	1,175	1,175	1,175
Sales ($millions)	12,859.1	12,859.1	12,859.1	12,859.1

Focusing again on results at market exchange rates, the average MIP-to-Canadian price ratio stood at 1.05 in 2011. (The corresponding value for 2010 was 1.06.) Results obtained with other multilateral measures are much as one would expect. Note that mean foreign prices produce higher foreign-to-Canadian price ratios than do MIPs. This is readily explained by the influence of US prices, which are typically much higher than prices elsewhere. Although US prices nearly always figure importantly in determining mean foreign price, they almost never emerge as median international prices.

Figure 10 puts these results in historical perspective, giving a history of the average MIP-to-Canadian price ratio from 2001 to 2011. Although there has been considerable movement in the ratio over this period, it has remained above parity.

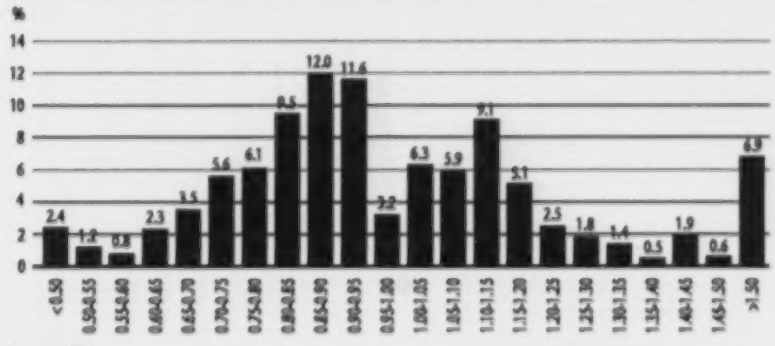
Figure 11 offers more detail on the product-level MIP-to-Canadian ratios underlying the averages reported in Table 12. This figure distributes the 2011 sales of each patented drug product according to the value of its MIP-to-Canadian price ratio (more exactly, according to the range into which the ratio fell).[16] These results show substantial dispersion in product-level price ratios: while patented drug products with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 27.1% of sales, those with ratios less than 0.90 accounted for 43.3% of sales, and products with ratios exceeding 1.10 accounted for 29.6%.

FIGURE 10 Average Ratio of Median International Price (MIP)-to-Canadian Price, At Market Exchange Rates, 2001–2011



Source: PMPRB

FIGURE 11 Range Distribution, Sales, by Median International Price (MIP)-to-Canadian Price Ratio, 2011



Source: PMPRB

15 The number of drug products and sales these ratios encompass vary because it is not always possible to find a matching foreign price for each patented drug product sold in Canada. Note that all of the bilateral average price ratios reported in Table 11 combined represent at least 82% of 2011 Canadian sales, while the multilateral ratios in Table 12 cover over 98%.

16 To produce the results represented in this figure, foreign prices were converted to their Canadian-dollar equivalents at market exchange rates.

Utilization of Patented Drug Products

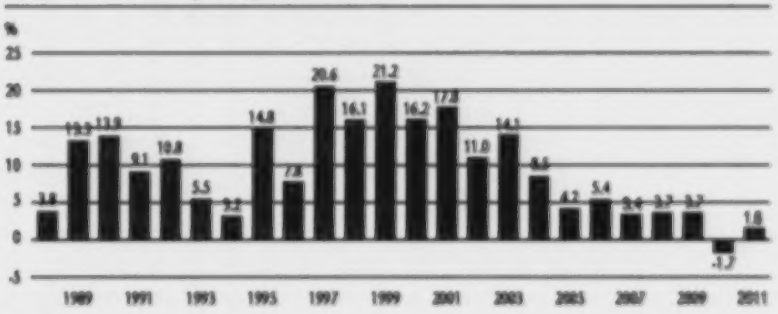
The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented drug products sold in Canada. The PMPRB maintains the Patented Medicines Quantity Index (PMQI) for this purpose. Figure 12 provides average rates of utilization growth, as measured by the PMQI, from 1988 through 2011. These results confirm that in recent years, growth in the utilization of patented drug products has declined significantly, with rates of utilization growth roughly tracking sales growth. This tracking pattern continued in 2011, with the utilization of patented drug products increasing by 1.6% and sales increasing by 1.7%.

Utilization Growth by Therapeutic Class

Table 13 provides average rates of utilization growth among patented drug products at the level of major therapeutic classes. The results in this table were obtained by applying the PMQI methodology to data segregated by ATC Level I class. As in Table 10, the last column provides an approximate decomposition of overall PMQI change into contributions attributable to each therapeutic class.

In 2011, levels of utilization remained the same or rose in all but three therapeutic classes. Modest growth in general antiinfectives for systemic use and antiparasitic products, cardiovascular system products and nervous system products accounted for most of the growth in overall utilization. Drug products in the genito-urinary system and sex hormones class also contributed appreciably to utilization growth.

FIGURE 12 Annual Rate of Quantity Change, Patented Medicines Quantity Index (PMQI), 1988–2011



Source: PMPRB

TABLE 13 Change in the Quantity, Patented Medicines Quantity Index (PMQI), by Major Therapeutic Class, 2011

Therapeutic class	Share: 2011 sales (%)	Quantity change: 2010 to 2011 (%)	Contribution to the PMQI (%)
A: Alimentary tract and metabolism	8.5	5.9	0.5
B: Blood and blood forming organs	7.2	-5.6	-0.4
C: Cardiovascular system	15.4	5.4	0.8
D: Dermatologicals	0.7	6.2	0.0
G: Genito-urinary system and sex hormones	4.2	15.7	0.7
H: Systemic hormonal preparations	0.6	11.0	0.1
J: General antiinfectives for systemic use and P: Antiparasitic products*	10.4	8.5	0.9
L: Antineoplastics and immunomodulating agents	23.3	-6.7	-1.6
M: Musculo-skeletal system	3.3	14.4	0.5
N: Nervous system	13.7	6.0	0.8
R: Respiratory system	8.8	-23.6	-2.1
S: Sensory organs	3.4	4.7	0.2
V: Various	0.5	4.0	0.0
All therapeutic classes	100.0	1.6	1.6

* These groups have been combined for reasons of confidentiality.

Source: PMPRB

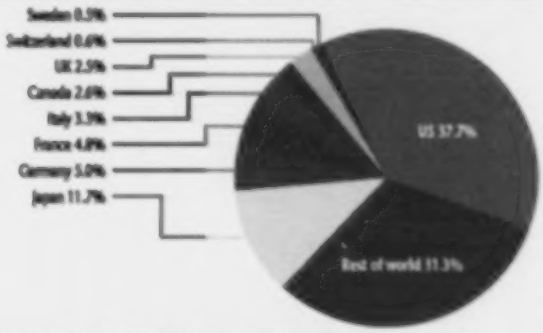
Canadian Drug Expenditures in the Global Context

IMS Health[17] regularly reports on drug sales across a large number of countries. Based on sales data from this source, Figure 13 provides shares of global sales for Canada and each of the seven comparator countries that the PMPRB considers in conducting its price reviews.[18] The Canadian market accounted for 2.6% of the global market in 2011.

Figure 14 provides Canada's share of global sales for each of the years 2005 through 2011. The Canadian share has remained between 2.4% and 2.7% throughout this period.

Figure 15 gives the average annual rate of growth in total drug sales for Canada and the seven comparator countries, individually and collectively. From 2005 to 2011, drug sales in Canada rose at an annual average rate of approximately 5.2%. Drug sales among the seven comparator countries rose at an annual average rate of 4.2% over the same period.

FIGURE 13 Distribution of Drug Sales Among Major National Markets, 2011



Source: MIDAS®, 2005–2011, IMS Health Incorporated or its affiliates. All rights reserved.[19]

FIGURE 14 Canada's Share of Drug Sales Among Major National Markets, 2005–2011

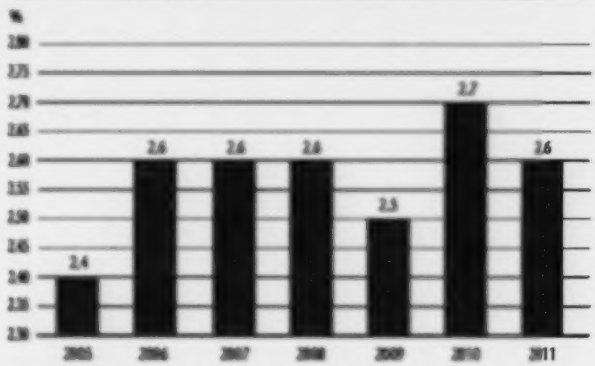


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FIGURE 15 Average Rate of Growth, Drug Sales, at Constant 2011 Market Exchange Rates, by Country, 2005–2011

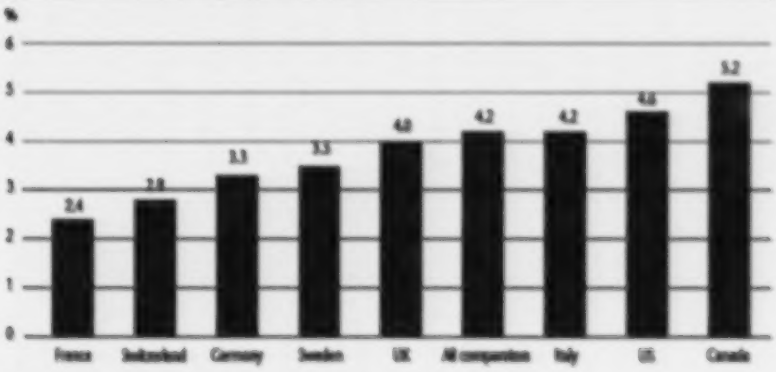

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Figure 16 compares rates of year-over-year growth in drug sales in Canada and the comparator countries combined. In 2011, for the second consecutive year, sales grew at a slower rate in Canada than in the comparator countries.

The proportion of national income allocated to the purchase of drug products provides another way to compare drug costs across countries.[20] Figure 17 gives drug expenditures as a share of Gross Domestic Product (GDP) for Canada and the seven comparator countries based on data for 2009. Drug expenditures absorbed between 1.1% and 2.1% of the GDP in the seven comparators. The Canadian value (1.9%) lies near the upper end of this range.

Table 14 provides historical perspective on the expenditures-to-GDP ratio. Between 2000 and 2009 drug expenditures in Canada grew at approximately twice the rate of GDP growth.

Table 15 gives the composition of patentees' sales by therapeutic class for Canada and the seven comparator countries, individually and as an aggregate.[21] These results imply a remarkable degree of similarity across countries.

FIGURE 16 Average Annual Rate of Change in Drug Sales, at Constant 2011 Market Exchange Rates, Canada and Comparator Countries, 2006–2011

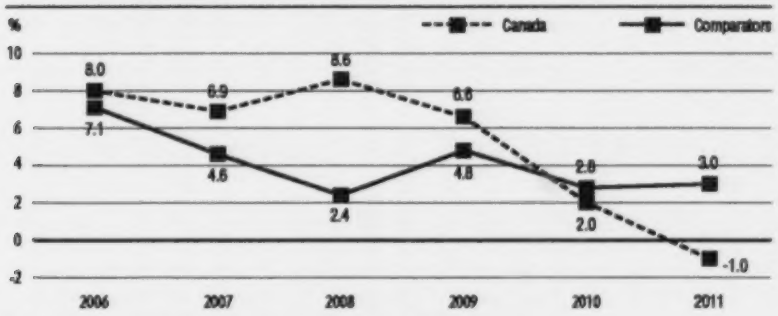

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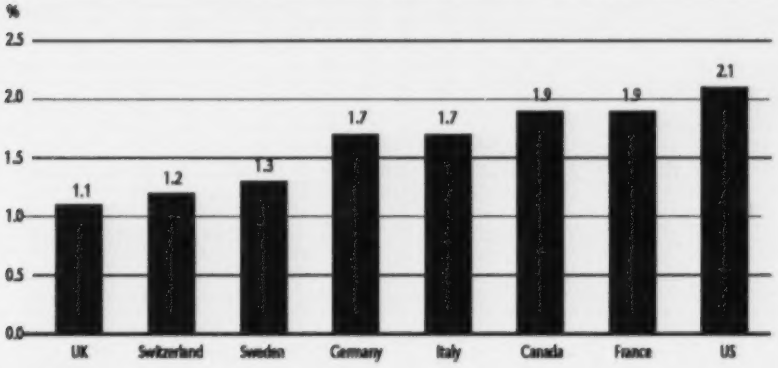
FIGURE 17 Pharmaceutical Expenditures as a Share of GDP, 2009



Source: OECD

TABLE 14 Drug Expenditures as a Share of GDP, 2009

	Share: Drug expenditures/ GDP, 2009 (%)	Share: Drug expenditures/ GDP, 2000 (%)	Growth: Drug expenditures 2000–2009 (%)	Growth: GDP 2000–2009 (%)
Canada	1.94	1.42	144.05	78.82
France	1.90	1.81	74.49	66.24
Germany	1.73	1.43	90.73	57.80
Italy	1.73	1.74	80.29	81.44
Sweden	1.25	1.18	52.81	44.25
Switzerland	1.15	1.11	50.86	45.44
United Kingdom	1.14	1.14	47.76	48.18
United States	2.09	1.46	105.74	43.86

Source: OECD

TABLE 15 Distribution of Drug Sales (%) by Major Therapeutic Class for Canada and Comparator Countries, 2011

Therapeutic Class	Canada	Comparators	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
A: Alimentary tract and metabolism	12.5	11.6	10.1	10.8	11.2	9.7	11.4	11.0	12.0
B: Blood and blood-forming organs	4.4	6.5	7.8	7.9	5.2	7.3	4.8	4.2	6.6
C: Cardiovascular system	17.0	11.8	13.9	15.4	10.8	7.6	13.6	10.8	11.4
D: Dermatologicals	3.1	2.5	2.3	2.2	2.6	2.3	3.7	3.1	2.5
G: Genito-urinary system and sex hormones	4.9	4.7	3.3	4.0	4.0	4.8	4.6	4.5	5.1
H: Systemic hormonal preparations	1.1	1.6	1.7	1.8	2.0	2.4	1.4	2.1	1.5
J: General antiinfectives for systemic use	6.8	10.4	11.6	13.2	9.7	7.6	10.8	9.8	10.2
L: Antineoplastics and immunomodulating agents	14.1	15.3	16.5	15.4	19.3	20.9	16.5	15.1	14.5
M: Musculo-skeletal system	3.7	3.0	3.7	4.1	3.6	2.9	5.0	2.5	2.8
N: Nervous system	18.4	18.7	14.7	12.2	16.2	19.3	16.6	19.4	20.0
P: Antiparasitic products	0.2	0.1	0.2	0.0	0.1	0.2	0.1	0.3	0.1
R: Respiratory system	7.2	7.8	6.4	6.0	6.9	8.8	6.3	10.0	8.1
S: Sensory organs	2.8	2.4	2.6	1.8	2.3	2.6	3.1	3.1	2.4
V: Various	3.9	3.6	5.4	5.3	6.0	3.7	2.0	4.1	2.9
All therapeutic classes	**100.0***	**100.0***	**100.0***	**100.0***	**100.0***	**100.0***	**100.0***	**100.0***	**100.0***

* Values in this column may not add to 100.0 due to rounding.

Source: MIDAS©, 2005–2011, IMS Health Incorporated or its affiliates. All rights reserved.[19]

17 Most of the statistical results presented in this section are based on sales data from MIDAS©, 2005–2011, IMS Health Incorporated or its affiliates. All rights reserved.[19] These data cover the pharmacy and hospital sectors.

18 The results given in Figures 13 through 16 are based on estimates of ex-factory sales revenues encompassing patented, non-patented branded and generic drug products. These estimates have been converted to Canadian-dollar equivalents at annual average market exchange rates. Fluctuations in these rates can substantially influence these shares.

19 Although based in part on data obtained under license from the MIDAS IMS database, the statements, findings, conclusions, views and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IMS AG.

20 Comparisons made on this basis will reflect international differences in prices, overall utilization and patterns of therapeutic choice, as well as differences in national income.

21 Note that the data used to produce Table 15 encompass patented, nonpatented branded and generic drug products. Hence, the results reported here for Canada are not directly comparable to those in Table 9, which encompass only patented drug products.

Analysis of Research and Development Expenditures

The *Patent Act* (Act) mandates the PMPRB to monitor and report on pharmaceutical research and development (R&D) spending (while giving the PMPRB no regulatory authority to consider the amount or type of patentees' research spending in the context of its price regulation). This chapter provides key statistics on the current state of pharmaceutical research investment in Canada.

Data Sources

The statistical results presented below were entirely derived from data that patentees have submitted to the PMPRB.

The Act requires each patentee to report its total gross revenues from sales of all drugs for human or veterinary use (including revenues from sales of non-patented drug products and from licensing agreements) and R&D expenditures in Canada related to medicines (both patented and non-patented for human or veterinary use). Patentees transmit this information to the PMPRB by means of its Form 3 (*Revenues and Research and Development Expenditures Provided Pursuant to subsection 88(1) of the Patent Act*).

The *Patented Medicines Regulations* (Regulations) require that each submitted Form 3 be accompanied by a certificate stating the information it contains is "true and correct". The Board does not audit Form 3 submissions, but it does review submitted data for anomalies and inconsistencies, seeking corrections or clarifications from patentees where necessary. To confirm that PMPRB staff has correctly interpreted the data submitted, each patentee is given the opportunity to review and confirm the accuracy of its own R&D-to-sales ratio before that ratio is published.

Failure to File

It is a patentee's responsibility to ensure a complete and accurate Form 3 is filed within the time frame set out in the Regulations. Where a patentee fails to meet these filing requirements, the Board may issue an Order demanding compliance. There were no such Board Orders issued for the 2011 reporting period.

Coverage

Note that companies without sales of patented medicines need not report to the PMPRB on their R&D expenditures. This has two implications.

First, the statistical results reported below should not be taken to cover all pharmaceutical research conducted in Canada. For example, a company may sell only non-patented drug products but may still perform considerable research in Canada. Similarly, a company may conduct research and have no product sales at all.[22] The results presented below will not reflect the R&D expenditures of firms in either situation.

Second, as new patented drug products come onto the Canadian market and existing patents expire, the number and identity of companies required to file R&D data may change from year to year. A total of 79 companies reported on their R&D activity in 2011. Of these, 33 were members of Canada's Research-Based Pharmaceutical Companies (Rx&D).

Definition of Sales Revenues

For reporting purposes, sales revenues are defined as total gross revenues from sales in Canada of all drug products and from licensing agreements (e.g., royalties and fees accruing to the patentee related to sales in Canada by licensees).

Definition of R&D Expenditures

Pursuant to section 6 of the Regulations, patentees are required to report R&D expenditures that would have qualified for an investment tax credit in respect to scientific research and experimental development (SR&ED) under the provisions of the *Income Tax Act* that came into effect on December 1, 1987. By this definition, R&D expenditures may include current expenditures, capital equipment costs and allowable depreciation expenses. Market research, sales promotions, quality control or routine testing of materials, devices or products and routine data collection are not eligible for an investment tax credit and, therefore, are not to be included in the R&D expenditures reported by patentees.

Total Sales Revenues and R&D Expenditures

Table 16 provides an overview of reported sales revenues and R&D expenditures over the period 1988 through 2011.

Patentees reported total 2011 sales revenues (Table 16) of $17.8 billion, an increase of 4.7% from 2010. Sales revenues reported by Rx&D members were $13.5 billion, accounting for 75.5% of the total. (Less than 1% of reported sales revenues were generated by licensing agreements.)

Patentees reported R&D expenditures of $991.7 million in 2011, a decrease of 15.8% over 2010. Rx&D members reported R&D expenditures of $901.2 million in 2011, a decrease of 9.9% over last year. Rx&D members accounted for 90.9% of all reported R&D expenditures in 2011.

TABLE 16 Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988–2011

	All Patentees					Rx&D					
Year	Number of companies reporting	R&D expenditures by all patentees ($millions)	Change from previous year (%)	Sales revenues ($millions)	Change from previous year (%)	R&D expenditures by Rx&D patentees ($millions)	Change from previous year (%)	Sales revenues by Rx&D patentees ($millions)	Change from previous year (%)	R&D-to-sales ratio: all patentees (%)	R&D-to-sales ratio: Rx&D patentees (%)
2011	79	991.7	-15.8	17,798.8	4.7	901.2	-9.9	13,446.1	10.7	5.6	6.7
2010	82	1,178.2	-7.4	17,000.0	-0.3	1,000.2	-11.7	12,149.0	-11.8	6.9	8.2
2009	81	1,272.0	-2.9	17,051.9	4.5	1,132.9	-3.4	13,780.0	4.6	7.5	8.2
2008	82	1,310.7	-1.1	16,316.7	2.0	1,172.2	-1.0	13,178.2	-1.4	8.1	8.9
2007	82	1,325.0	9.5	15,991.0	7.3	1,184.4	24.8	13,359.8	20.0	8.3	8.9
2006	72	1,210.0	-1.9	14,902.0	4.7	949.0	-8.8	11,131.2	-5.8	8.1	8.5
2005	80	1,234.3	5.5	14,231.3	0.5	1,040.1	3.9	11,821.4	0.0	8.7	8.8
2004	84	1,170.0	-2.0	14,168.3	4.0	1,000.8	0.8	11,819.0	8.8	8.3	8.5
2003	83	1,194.3	-0.4	13,631.1	12.8	992.9	-3.6	10,865.7	5.2	8.8	9.1
2002	79	1,198.7	13.0	12,081.2	12.5	1,029.6	10.1	10,323.8	16.8	9.9	10.0
2001	74	1,060.1	12.6	10,732.1	15.3	935.2	14.7	8,835.4	14.3	9.9	10.6
2000	79	941.8	5.3	9,309.6	12.0	815.5	4.0	7,728.8	11.6	10.1	10.6
1999	78	894.6	12.0	8,315.5	19.2	784.3	9.9	6,923.4	22.8	10.8	11.3
1998	74	798.9	10.2	6,975.2	10.9	713.7	8.6	5,640.2	10.6	11.5	12.7
1997	75	725.1	9.0	6,288.4	7.4	657.4	10.3	5,098.2	4.9	11.5	12.9
1996	72	665.3	6.4	5,857.4	9.9	595.8	6.5	4,859.5	8.7	11.4	12.3
1995	71	625.5	11.5	5,330.2	7.5	559.5	9.8	4,468.8	1.4	11.7	12.5
1994	73	561.1	11.4	4,957.4	4.4	509.5	10.4	4,407.2	2.0	11.3	11.6
1993	70	503.5	22.1	4,747.6	14.0	461.4	24.0	4,321.4	14.4	10.6	10.7
1992	71	412.4	9.6	4,164.4	6.9	372.1	9.0	3,778.4	6.5	9.9	9.8
1991	65	376.4	23.2	3,894.8	18.1	341.4	24.7	3,546.9	19.5	9.7	9.6
1990	65	305.5	24.8	3,298.8	11.0	273.8	25.8	2,967.9	10.5	9.3	9.2
1989	66	244.8	47.4	2,973.0	9.4	217.6	34.7	2,685.5	7.3	8.2	8.1
1988	66	165.7	—	2,718.0	—	161.5	—	2,502.3	—	6.1	6.5

Source: PMPRB

R&D-to-Sales Ratios

Table 16 also provides ratios of R&D expenditures to sales revenues. It should be noted in this context that, with the adoption of the 1987 amendments to the Act, Rx&D made a public commitment to increase their annual R&D expenditures to 10% of sales revenues by 1996.[23] This level of R&D expenditure was obtained by 1993, in some years exceeding 10%. However, since 2003, R&D-to-sales ratios for all patentees and for Rx&D members have declined.

The ratio of R&D expenditures to sales revenues among all patentees was 5.6% in 2011, down from 6.9% in 2010. These values are close to figures last observed in 1988. The overall R&D-to-sales ratio has been less than 10% for the past 11 consecutive years.

The corresponding R&D-to-sales ratio for members of Rx&D was 6.7% in 2011, down from 8.2% in 2010.[24] These values are close to figures last observed in 1988. The Rx&D ratio has been less than 10% for the past nine consecutive years.

Table 21 in Appendix 3 provides details on the range of 2011 R&D-to-sales ratios. Of the 79 companies reporting in 2011, 84.8% had R&D-to-sales ratios below 10%.

New Developments

Rx&D and the Canadian Institutes for Health Research (CIHR) jointly funded a KPMG survey on R&D and other investments made by Rx&D member companies. KPMG's report, entitled *Summary of Pharmaceutical Survey Findings on R&D Spending and Investments by Rx&D Members – 2010*, was posted on CIHR's website in June 2011. Rx&D has indicated that it intends to conduct a similar survey for 2011.

In October 2011, the Expert Panel leading the Review of Federal Support to R&D submitted its final report to the Minister of State for Science and Technology. The "Jenkins Report" made a series of recommendations that called for a simplified and more focused approach to the R&D funding provided by the federal government every year.

Budget 2012 proposed reductions to the Scientific Research and Experimental Development (SR&ED) tax credit and new restrictions on deductions. It also introduced new measures to support innovation and R&D.

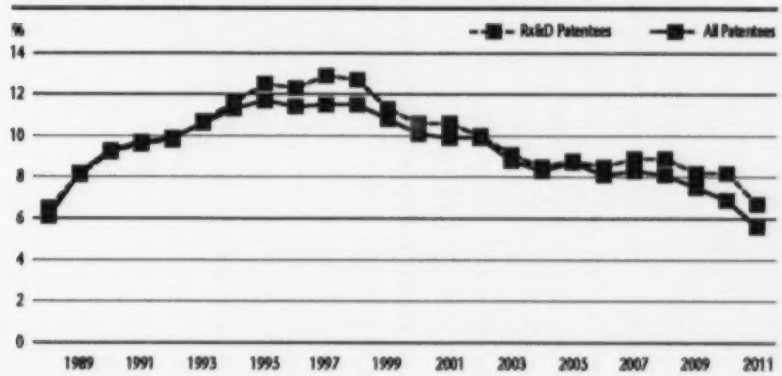
Current Expenditures by Type of Research

Table 17 and Figure 19 (as well as Figure 21 in Appendix 3) provide information on the allocation of 2011 current R&D expenditures[25] among basic and applied research and other qualifying R&D.[26] Patentees reported spending $164.9 million on basic research in 2011, representing 17.3% of current R&D expenditures and a decline of 30.1% over the previous year. Patentees reported spending $525.1 million on applied research, representing 55.0% of current R&D expenditures. Clinical trials accounted for 75.2% of applied research expenditures.

Current R&D Expenditures by Performer

Patentees report expenditures on research they conduct themselves (intramural) and research performed by other establishments, such as universities, hospitals and other manufacturers (extramural). Table 18 shows that 51.9% of 2011 current research expenditures were intramural. Research performed by other companies on behalf of patentees was 20.6% of current expenditures, while research conducted in universities and hospitals accounted for 15.9%.

FIGURE 18 R&D-to-Sales Ratio, Pharmaceutical Patentees, 1988–2011



Source: PMPRB

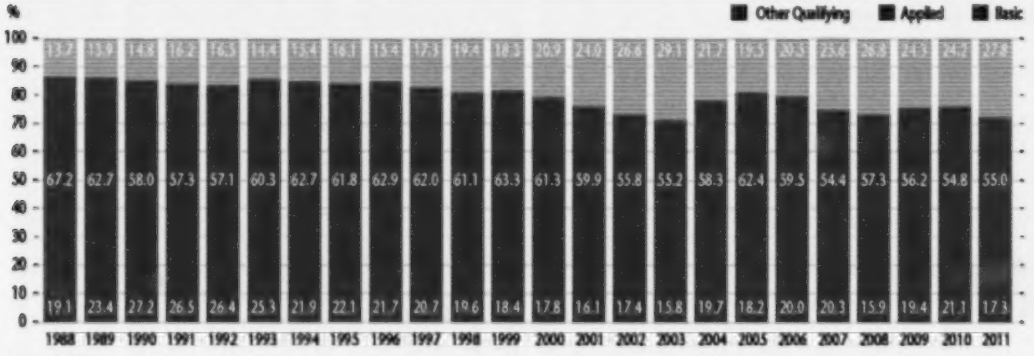
TABLE 17 Current R&D Expenditures by Type of Research, 2011 and 2010

Type of research	Expenditures: 2011 ($millions)	Share: 2011 (%)	Expenditures: 2010 ($millions)	Share: 2010 (%)	Annual change in expenditures (%)
Basic	**164.9**	**17.3**	**235.9**	**21.1**	**-30.1**
Chemical	99.4	10.4	119.8	10.7	-17.0
Biological	65.5	6.9	116.1	10.4	-43.6
Applied	**525.1**	**55.0**	**613.4**	**54.6**	**-14.4**
Manufacturing Process	77.4	8.1	86.7	7.8	-10.7
Pre-Clinical Trial I	16.9	1.8	8.9	0.8	89.9
Pre-Clinical Trial II	35.7	3.8	52.8	4.7	-32.4
Clinical Trial Phase I	29.8	3.1	33.9	3.0	-12.1
Clinical Trial Phase II	83.0	8.7	113.3	10.1	-26.7
Clinical Trial Phase III	282.3	29.5	317.8	28.4	-11.2
Other Qualifying R&D	**265.2**	**27.8**	**270.8**	**24.3**	**-2.1**
Total	**955.3**	**100.0***	**1,120.1**	**100.0***	**-14.7**

* Values in this column may not add to 100.0 due to rounding.

Source: PMPRB

FIGURE 19 Current R&D Expenditures by Type of Research, 1988–2011



Source: PMPRB

TABLE 18 Current R&D Expenditures by R&D Performer, 2011 and 2010

R&D performer	Expenditures: 2011 ($millions)	Share: 2011 (%)	Expenditures: 2010 ($millions)	Share: 2010 (%)	Annual increase in expenditures (%)
Intramural					
Patentees	496.1	51.9	575.1	51.4	-13.7
Extramural					
Universities and hospitals	151.7	15.9	160.9	14.4	-5.7
Other companies	196.9	20.6	241.7	21.6	-18.6
Others	110.6	11.6	142.4	12.6	-22.3
Total	**955.3**	**100.0***	**1,120.1**	**100.0***	**-14.7**

* Values in this column may not add to 100.0 due to rounding.

Source: PMPRB

Current R&D Expenditures by Source of Funds

Table 19 provides information on the sources of funds used by patentees to finance their R&D activity. Internal company funds remained by far the single largest source of funding in 2011, accounting for 88.6% of current expenditures. Funds received from government amounted to 2.9% of current expenditures.

Current R&D Expenditures by Region

Table 20 (as well as Table 23 and Table 24 in Appendix 3) show current R&D expenditures by region. As in previous years, current expenditures were heavily concentrated in Ontario and Quebec in 2011, with these provinces accounting for 85.3% of total expenditures. While current R&D expenditures decreased at a year-over-year rate of 12.9% in Western Canada, they also declined in Ontario by 19.4% and in Quebec by 10.7%.

TABLE 19 Total R&D Expenditures by Source of Funds, 2011 and 2010

Source of funds	Expenditures: 2011 ($millions)	Share: 2011 (%)	Expenditures: 2010 ($millions)	Share: 2010 (%)	Annual increase in expenditures (%)
Company funds	879.2	88.6	1,050.8	89.2	-16.3
Federal/provincial governments	28.7	2.9	36.3	3.1	-20.9
Others	83.8	8.5	91.1	7.7	-8.0
Total	991.7	100.0*	1,178.2	100.0*	-15.8

* Values in this column may not add to 100.0 due to rounding.

Source: PMPRB

TABLE 20 Current R&D Expenditures by Region, 2011 and 2010

Region	Expenditures: 2011 ($millions)	Share: 2011 (%)	Expenditures: 2010 ($millions)	Share: 2010 (%)	Annual increase in expenditures (%)
Atlantic provinces	17.9	1.9	18.1	1.6	-0.6
Quebec	411.8	43.1	461.2	41.2	-10.7
Ontario	403.0	42.2	500.2	44.7	-19.4
Western provinces	122.5	12.8	140.6	12.6	-12.9
Territories	0.0	0.0	0.0	0.0	0.0
Total	955.3	100.0*	1,120.1	100.0*	-14.7

* Values in this column may not add to 100.0 due to rounding.

Source: PMPRB

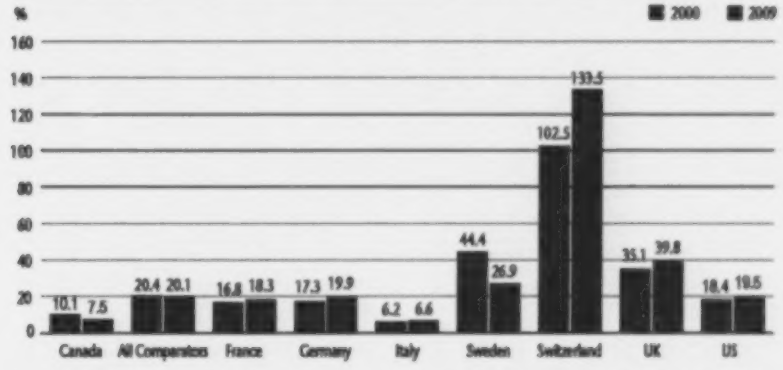
The Global Context

Figure 20 compares Canadian pharmaceutical R&D-to-sales ratios for the years 2000 and 2009 to those in the PMPRB's seven comparator countries.[27] Canada's ratio stood at 10.1% in 2000. Only Italy, at 6.2%, had a lower ratio in that year, while Switzerland had the highest ratio at 102.5%.

A similar pattern emerges in the ratios for 2009. Italy remained at the bottom of the range at 6.6%, with Canada second lowest at 7.5%. Ratios in all other comparator countries remained well above Canada's ratio. The ratio obtained by aggregating R&D spending and sales across all seven comparator countries was 20.1%, two and a half times the value obtained for Canada.

The R&D-to-sales ratios represented in Figure 20 may be compared to the average bilateral price ratios reported in Table 11 (see *Comparison of Canadian Prices to Foreign Prices* section). Several comparator countries, which have patented drug prices that are, on average, substantially less than prices in Canada, have achieved R&D-to-sales ratios well above those in Canada.

FIGURE 20 R&D-to-Sales Ratios, Canada and Comparator Countries



Source: PMPRB; European Federation of Pharmaceutical Industries and Associations (EFPIA): *The Pharmaceutical Industry in Figures 2011*

22 This is likely the situation for much of Canada's biotechnology sector. Note, however, that if a patentee commissions research from another company specializing in biotechnology research, the patentee should normally include this among the research expenditures that it reports to the PMPRB.

23 As published in the Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations*, 1988, published in the *Canada Gazette*, Part II, Vol. 122, No. 20 – SOR/DORS/88-474.

24 The R&D-to-sales ratios presented in Table 16 include research expenditures funded by government grants. If the government-funded component is excluded, the ratios for all patentees and for the members of Rx&D in 2011 are 5.4% and 6.5%, respectively.

25 Current R&D expenditures consist of non-capital expenses directly related to research, including (*a*) wages and salaries; (*b*) direct material; (*c*) contractors and sub-contractors; (*d*) other direct costs such as factory overhead; (*e*) payments to designated institutions; (*f*) payments to granting councils; and (*g*) payments to other organizations. These elements are described in more detail in Form 3 ("Revenues and Research and Development Expenditures") available from the PMPRB website under the heading Legislation, Regulations and Guidelines/Patentee's Guide to Reporting. Current R&D expenditures accounted for 96.3% of total R&D expenditure in 2011, while capital equipment costs and allowable depreciation expenses made up 2.1% and 1.6%, respectively.

26 "Basic research" is defined as work that advances scientific knowledge without a specific application in mind. "Applied research" is directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials and clinical trials. "Other qualifying research" includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

27 Sales in Figure 20 represent domestic sales and do not include exports.

National Prescription Drug Utilization Information System

Background

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001.

Its purpose is to provide policy makers and public drug plan managers with critical analyses of price, utilization and cost trends, so that Canada's health care system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost increases.

The PMPRB's authority to conduct work under the NPDUIS initiative is based on a formal request by the federal Minister of Health under section 90 of the *Patent Act*, and is consistent with the PMPRB's mandate to report on pharmaceutical trends.

The NPDUIS Steering Committee, composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and Health Canada, advises the PMPRB on its research agenda and on individual studies.

Highlights

The PMPRB published five NPDUIS reports in 2011. The reports, listed below, are available on the PMPRB website.

- *New Drug Pipeline Monitor – Third Edition* (July 2011)
  This report identifies drugs currently under development that may have an impact on future public drug plan expenditures.
- *Generic Drugs in Canada: International Price Comparisons and Potential Cost Savings* (September 2011)
  This report compares the 2008 prices of generic drug products in Canada to prices in seven other industrialized countries, and estimates the potential savings that might be realized by public drug plans if Canadian prices were brought into line with foreign prices.
- *Public Drug Plan Dispensing Fees: A Cost-Driver Analysis, 2001/02 to 2007/08* (September 2011)
  This analytical report investigates, quantifies and explains the factors driving costs related to dispensing fees from 2001/02 to 2007/08.
- *The Impact of Generic Entry on the Utilization of the Ingredient* (September 2011; Revised May 2012)
  Using the public drug plan data, this report employs a case-study approach to analyze the impact of generic competition on the utilization of the ingredient.
- *Wholesale Up-charge Policies of Canada's Public Drug Plans* (December 2011; Revised January 2012)
  This report provides a snapshot of how public drug plans regulate the percentage markup charged on prescription drugs sourced via wholesalers or other distributors.

The NPDUIS Steering Committee held its annual meeting in Ottawa in October 2011. The meeting provided an opportunity to share the results of completed and ongoing research studies, discuss priorities for future research, and engage with members of the Pharmaceutical Policy Research Collaboration (PPRC), a publicly funded network of university-based researchers from across Canada.

Patented Medicine Prices Review Board

Appendicies

Appendix 1: Glossary

For more detailed information and definitions please refer to the Patent Act, the Patented Medicines Regulations, the PMPRB Compendium of Policies, Guidelines and Procedures, and the Food and Drug Regulations, or contact the PMPRB.

Active Ingredient: Chemical or biological substance responsible for the claimed pharmacologic effect of a drug product.

Advance Ruling Certificate (ARC): Under the *Patent Act*, the Board may issue a non-binding Advance Ruling Certificate on the price of a patented drug product at the request of the patentee. This requires the patentee to clearly establish that the proposed price of the patented drug product would not exceed the Board's Guidelines.

ATC: Anatomical Therapeutic Chemical (ATC) classification system, developed and maintained by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology, divides drugs into different groups according to their site of action and therapeutic and chemical characteristics. This system is used by the PMPRB as a guide for selecting comparable medicines for purposes of price review.

Dedication of Patent: A practice whereby a patentee notifies the Commissioner of Patents that it has surrendered its rights and entitlements flowing from the patent for the benefit of the public to use and enjoy. NB: As of January 30, 1995, the Board does not recognize dedication of patent as a means to remove the medicine from its jurisdiction.

Drug Identification Number (DIN): A registration number (drug identification number) that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the *Food and Drugs Regulations*. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and route of administration.

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s).

Failure to File: The complete or partial failure of a patentee to comply with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

Failure to Report: The complete failure of a patentee to have reported a patented drug product being sold in accordance with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

Generic Product: A drug product with the same active ingredient, strength and dosage form of a brand name drug product.

License, Voluntary: A contractual agreement between a patent holder and a licensee under which the licensee is entitled to enjoy the benefit of the patent or to exercise any rights in relation to the patent for some consideration (i.e., royalties in the form of a share of the licensee's sales).

Medicine: Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered in vivo in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans and or animals, however administered. For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used in vivo, regardless of delivery mechanism (e.g., transdermal, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, in vitro diagnostic products and disinfectants that are not used in vivo.

Notice of Compliance (NOC): A notice in respect of a medicine issued by the Health Products and Food Branch of Health Canada under section C.08.004 of the *Food and Drugs Regulations*. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the product is approved for sale in Canada.

Patent: An instrument issued by the Commissioner of Patents in the form of letters patent for an invention that provides its holder with a monopoly limited in time, for the claims made within the patent. A patent gives its holder and its legal representatives the exclusive right of making, constructing and using the invention and selling it to others to be used.

Patented Medicine Price Index (PMPI): The PMPI was developed by the PMPRB as a measure of average year-over-year change in the transaction prices of patented drug products sold in Canada, based on the price and sales information reported by patentees.

Patentee: As defined by subsection 79(1) of the *Patent Act*, "the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act* Amendment Act, 1992, that other person in respect of those rights;"

Pending Patent: An application for a patent that has not yet been issued.

Research and Development (R&D): Basic or applied research for the purpose of creating new, or improving existing, materials, devices, products or processes (e.g., manufacturing processes).

Research and Development – Applied Research: R&D directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials and clinical trials.

Research and Development – Basic Research: R&D defined as work that advances scientific knowledge without a specific application in mind.

Research and Development – Other Qualifying: Includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development". It includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

Research and Development Expenditures: For the purposes of the *Patented Medicines Regulations*, in particular Sections 5 and 6, research and development includes activities for which expenditures would have qualified for the investment tax credit for scientific research and experimental development under the *Income Tax Act* as it read on December 1, 1987.

Current Research and Development Expenditures: Consist of the following non-capital expenses that are directly related to research work: (a) wages and salaries, (b) direct material, (c) contractors and subcontractors, (d) other direct costs such as factory overhead, (e) payments to designated institutions, (f) payments to granting councils, and (g) payments to other organizations. These elements are described in greater detail in the *Patentee's Guide to Reporting* – Form 3, available from the PMPRB website under Legislation, Regulations and Guidelines/Patentee's Guide to Reporting.

Special Access Programme (SAP): A program operated by Health Canada to give practitioners access to drugs that are not approved or otherwise available for sale in Canada.

Voluntary Compliance Undertaking (VCU): A written undertaking by a patentee to adjust its price to comply to the Board's Guidelines. The Chairperson may approve a VCU in lieu of issuing a Notice of Hearing if it is in the public interest. A VCU can also be submitted following the issuance of a Notice of Hearing. A VCU submitted at this point must be approved by the Board Hearing Panel struck to hear the matter. The Board reports publicly on all VCUs approved by the Chairperson or the Board.

Appendix 2: Patented Drug Products First Reported to the PMPRB in 2011

Brand name	Company	DIN	Status	Level of therapeutic improvement/category*
Abstral – 100 mcg/tablet	Paladin Labs Inc.	02364174	Within Guidelines	MI-S
Abstral – 200 mcg/tablet	Paladin Labs Inc.	02364182	Within Guidelines	SN
Abstral – 300 mcg/tablet	Paladin Labs Inc.	02364190	Within Guidelines	SN
Abstral – 400 mcg/tablet	Paladin Labs Inc.	02364204	Within Guidelines	SN
Abstral – 600 mcg/tablet	Paladin Labs Inc.	02364212	Within Guidelines	SN
Abstral – 800 mcg/tablet	Paladin Labs Inc.	02364220	Within Guidelines	SN
Actonel DR – 35 mg/tablet	Warner Chilcott Canada Co.	02370417	Within Guidelines	MI-S
Aczone – 50 mg/gm	Valeant Canada LP	02281074	Within Guidelines	SN
Adacel – Polio	sanofi pasteur Limited	02352044	Within Guidelines	SN
Afinitor – 2.5 mg/tablet	Novartis Pharma Canada Inc.	02369257	Within Guidelines	SN
Afinitor – 5 mg/tablet	Novartis Pharma Canada Inc.	02339501	Within Guidelines	SN
Banzel – 100 mg/tablet	Eisai Limited	02369613	Subject to Investigation	SN
Banzel – 200 mg/tablet	Eisai Limited	02369621	Subject to Investigation	SN
Banzel – 400 mg/tablet	Eisai Limited	02369648	Subject to Investigation	SN
Benlysta – 120 mg/vial	GlaxoSmithKline Inc.	02370050	Within Guidelines	MI-P
Benlysta – 400 mg/vial	GlaxoSmithKline Inc.	02370069	Within Guidelines	MI-P
Biacna 1.2/0.025	Valeant Canada LP	02359685	Within Guidelines	SN
Brilinta – 90 mg/tablet	AstraZeneca Canada Inc.	02368544	Within Guidelines	MI-P
Byetta – 5 mcg/dose	Eli Lilly Canada Inc.	02361809	Within Guidelines	SN
Byetta – 10 mcg/dose	Eli Lilly Canada Inc.	02361817	Within Guidelines	SN
Complera 200/300/25 – 525 mg/tablet	Gilead Sciences Inc.	02374129	Within Guidelines	SN
Daxas – 500 mcg/tablet	Nycomed Canada Inc	02359456	Subject to Investigation	SN
Docetaxel – 10 mg/ml	Hospira Healthcare Corporation (Canada)	02361957	Within Guidelines	SN
Edurant – 25 mg/tablet	Janssen Inc.	02370603	Within Guidelines	SN
Emend IV – 150 mg/vial	Merck Canada Inc.	02363356	Within Guidelines	SN
Evicel	Johnson & Johnson Medical Products	02348497	Within Guidelines	SN
Feiba NF 2500	Baxter Corporation	02353903	Within Guidelines	SN
Firazyr – 20 mg/syringe	Shire Human Genetic Therapies Inc.		Does Not Trigger Investigation	MI-S
Gilenya – 0.5 mg/capsule	Novartis Pharma Canada Inc.	02365480	Within Guidelines	MI-P
Halaven – 0.5 mg/ml	Eisai Limited	02377438	Subject to Investigation	MI-P
Hizentra - 200 mg/ml	CSL Behring Inc.	02370352	Within Guidelines	SN
Ilaris – 150 mg/vial	Novartis Pharma Canada Inc.	02344939	Within Guidelines	B
Jalyn 0.5/0.4 – 0.9 mg/capsule	GlaxoSmithKline Inc.	02372010	Within Guidelines	SN
Jevtana – 60 mg/vial	sanofi-aventis Canada Inc.	02369524	Within Guidelines	MI-P
Luveris – 75 mg/vial	EMD Serono Canada Inc.	02269066	Subject to Investigation	Category 3
Menactra	sanofi pasteur Limited	02279924	Does Not Trigger Investigation	Category 3

Brand name	Company	DIN	Status	Level of therapeutic improvement/category*
Menveo – 63.8 mcg/dose	Novartis Pharma Canada Inc.	02347393	Within Guidelines	SN
Mozobil – 20 mg/ml	Genzyme Canada Inc.	02377225	Within Guidelines	MI-P
Norvir – 100 mg/tablet	Abbott Laboratories Limited	02357593	Does Not Trigger Investigation	SN
Nucynta CR – 50 mg/tablet	Janssen Inc.	02360373	Within Guidelines	MI-P
Nucynta CR – 100 mg/tablet	Janssen Inc.	02360381	Within Guidelines	MI-P
Nucynta CR – 150 mg/tablet	Janssen Inc.	02360403	Within Guidelines	MI-P
Nucynta CR – 200 mg/tablet	Janssen Inc.	02360411	Within Guidelines	MI-P
Nucynta CR – 250 mg/tablet	Janssen Inc.	02360438	Within Guidelines	MI-P
Oleptro – 150 mg/caplet	Labopharm Inc.	02361868	Within Guidelines	SN
Oleptro – 300 mg/caplet	Labopharm Inc.	02361876	Within Guidelines	SN
Onsolis – 200 mcg/film	Meda Valeant Pharma Canada Inc.	02350661	Within Guidelines	MI-S
Onsolis – 400 mcg/film	Meda Valeant Pharma Canada Inc.	02350688	Within Guidelines	MI-S
Onsolis – 600 mcg/film	Meda Valeant Pharma Canada Inc.	02350696	Within Guidelines	MI-S
Onsolis – 800 mcg/film	Meda Valeant Pharma Canada Inc.	02350718	Within Guidelines	MI-S
Onsolis – 1200 mcg/film	Meda Valeant Pharma Canada Inc.	02350726	Within Guidelines	MI-S
Oxyneo – 10 mg/tablet	Purdue Pharma	02372525	Within Guidelines	SN
Oxyneo – 15 mg/tablet	Purdue Pharma	02372533	Within Guidelines	SN
Oxyneo – 20 mg/tablet	Purdue Pharma	02372797	Within Guidelines	SN
Oxyneo – 30 mg/tablet	Purdue Pharma	02372541	Within Guidelines	SN
Oxyneo – 40 mg/tablet	Purdue Pharma	02372568	Within Guidelines	SN
Oxyneo – 60 mg/tablet	Purdue Pharma	02372576	Within Guidelines	SN
Oxyneo – 80 mg/tablet	Purdue Pharma	02372584	Within Guidelines	SN
Ozurdex – 0.7 mg/implant	Allergan Inc.	02363445	Within Guidelines	SN
Pataday – 2 mg/ml	Alcon Canada Inc.	02362171	Does Not Trigger Investigation	SN
Pat-Galantamine ER – 8 mg/capsule	Patriot, A Division of Janssen Inc.	02316943	Subject to Investigation	SN
Pat-Galantamine ER – 16 mg/capsule	Patriot, A Division of Janssen Inc.	02316951	Subject to Investigation	SN
Pat-Galantamine ER – 24 mg/capsule	Patriot, A Division of Janssen Inc.	02316978	Subject to Investigation	SN
Rapaflo – 4 mg/capsule	Watson Pharma Company	02361643	Does Not Trigger Investigation	SN
Rapaflo – 8 mg/capsule	Watson Pharma Company	02361651	Does Not Trigger Investigation	SN
Renvela – 800 mg/tablet	Genzyme Canada Inc.	02354586	Within Guidelines	SN
Revolade – 25 mg/tablet	GlaxoSmithKline Inc.	02361825	Does Not Trigger Investigation	MI-S
Revolade – 50 mg/tablet	GlaxoSmithKline Inc.	02361833	Does Not Trigger Investigation	MI-S
Seasonique 0.15/0.03/0.01	Warner Chilcott Canada Co.	02344176	Within Guidelines	SN
Sprycel – 80 mg/tablet	Bristol-Myers Squibb Canada Co.	02360810	Does Not Trigger Investigation	SN
Sprycel – 140 mg/tablet	Bristol-Myers Squibb Canada Co.	02360829	Does Not Trigger Investigation	SN
Stayn – 10 mg/tablet	Bayer Inc.	02372436	Within Guidelines	SN
Sublinox – 10 mg/tablet	Valeant Canada LP	02370433	Within Guidelines	SN
Tactuo 1/25 – 26 mg/gm	Galderma Canada Inc.	02365871	Subject to Investigation	MI-S
Tasigna – 150 mg/capsule	Novartis Pharma Canada Inc.	02368250	Within Guidelines	SN
Thalomid – 100 mg/capsule	Celgene Corporation	02355205	Within Guidelines	SN
Thalomid – 200 mg/capsule	Celgene Corporation	02355221	Within Guidelines	SN
Taxol VHSD Kit – 500 unit/ml	Baxter Corporation	02326175	Within Guidelines	SN

Brand name	Company	DIN	Status	Level of therapeutic improvement/category*
Tobi Podhaler – 28 mg/capsule	Novartis Pharma Canada Inc.	02365154	Subject to Investigation	MI-S
Toctino – 10 mg/capsule	Actelion Pharmaceuticals Canada Inc.	02337630	Within Guidelines	SN
Trajenta – 5 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02370921	Within Guidelines	SN
Twynsta 40/5 – 45 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02371022	Within Guidelines	SN
Twynsta 40/10 – 50 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02371030	Within Guidelines	SN
Twynsta 80/5 – 85 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02371049	Within Guidelines	SN
Twynsta 80/10 – 90 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02371057	Within Guidelines	SN
Vectibix – 20 mg/ml	Amgen Canada Inc.	02308487	Within Guidelines	Category 3
Verdeso – 0.5 mg/gm	GlaxoSmithKline Inc.	02348489	Within Guidelines	SN
Victrelis Triple 200/200/80	Merck Canada Inc.	02371448	Within Guidelines	SI
Victrelis Triple 200/200/100	Merck Canada Inc.	02371456	Within Guidelines	SI
Victrelis Triple 200/200/120	Merck Canada Inc.	02371464	Within Guidelines	SI
Victrelis Triple 200/200/150	Merck Canada Inc.	02371472	Within Guidelines	SI
Vimovo 20/375 – 395 mg/tablet	AstraZeneca Canada Inc.	02361701	Within Guidelines	SN
Vimovo 20/500 – 520 mg/tablet	AstraZeneca Canada Inc.	02361728	Within Guidelines	SN
Vimpat IV – 10 mg/ml	UCB Canada Inc.	02357666	Within Guidelines	SN
Viramune XR – 400 mg/tablet	Boehringer Ingelheim (Canada) Ltd.	02367289	Within Guidelines	SN
Votrient – 200 mg/tablet	GlaxoSmithKline Inc.	02352303	Within Guidelines	SN
Vyvanse – 20 mg/capsule	Shire Canada Inc.	02347156	Within Guidelines	SN
Vyvanse – 30 mg/capsule	Shire Canada Inc.	02322951	Within Guidelines	Category 3
Vyvanse – 40 mg/capsule	Shire Canada Inc.	02347164	Within Guidelines	SN
Vyvanse – 50 mg/capsule	Shire Canada Inc.	02322978	Subject to Investigation	Category 3
Vyvanse – 60 mg/capsule	Shire Canada Inc.	02347172	Subject to Investigation	SN
Xgeva – 120 mg/vial	Amgen Canada Inc.	02368153	Within Guidelines	MI-S
Yervoy – 5 mg/ml	Bristol-Myers Squibb Canada Co.	02379384	Within Guidelines	SI
Zenhale 50/5 – 55 mcg/dose	Merck Canada Inc.	02361744	Within Guidelines	SN
Zenhale 100/5 – 105 mcg/dose	Merck Canada Inc.	02361752	Within Guidelines	SN
Zenhale 200/5 – 205 mcg/dose	Merck Canada Inc.	02361760	Within Guidelines	SN
Zytiga – 250 mg/tablet	Janssen Inc.	02371065	Within Guidelines	MI-S
Zytram XL – 75 mg/tablet	Purdue Pharma	02360322	Within Guidelines	SN
Zytram XL – 100 mg/tablet	Purdue Pharma	02360349	Within Guidelines	SN

* *Sold after implementation of new Guidelines in 2010:*

- **SN** Slight or No Improvement
- **MI-S** Moderate Improvement – Secondary
- **MI-P** Moderate Improvement – Primary
- **SI** Substantial Improvement
- **B** Breakthrough

Sold prior to implementation of new Guidelines in 2010:

- **Category 1** An existing or comparable dosage form of an existing medicine
- **Category 2** A non-comparable dosage form of an existing medicine, or the first DIN of a new chemical entity that is a breakthrough or provides a substantial improvement over comparable existing DINs
- **Category 3** A non-comparable dosage form of an existing medicine, or the first DIN of a new chemical entity that provides moderate, little or no therapeutic advantage over comparable existing DINs

Appendix 3: Research and Development

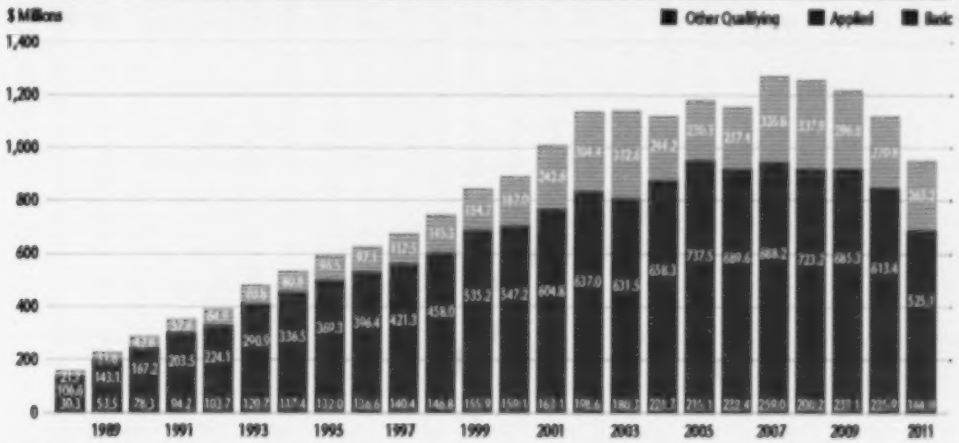
TABLE 21 Range of R&D-to-Sales Ratios by Number of Reporting Companies and Total Sales Revenue

Range: R&D-to-Sales Ratio	Number of reporting companies: 2011	Sales revenues: 2011 ($millions)	Share: 2011 (%)	Number of reporting companies: 2010	Sales revenues: 2010 ($millions)	Share: 2010 (%)
0%	30	1,625.4	9.1	26	628.0	3.7
≤ 10%	37	12,995.1	73.0	41	12,349.0	72.6
> 10%	12	3,178.3	17.9	15	4,023.0	23.7
Total	**79**	**17,798.8**	**100.0***	**82**	**17,000.0**	**100.0***

* Values in this column may not add to 100.0 due to rounding.

Source: PMPRB

FIGURE 21 Current R&D Expenditures by Type of Research, 1988–2011



Source: PMPRB

TABLE 22 Ratios of R&D Expenditures to Sales Revenue by Reporting Patentee[1], 2011 and 2010

Company	R&D-to-sales ratio (%) 2011	2010
Abbott Laboratories, Ltd.[2,4]	1.1	1.6
Actelion Pharmaceutiques Canada Inc.[2]	5.9	8.8
Alcon Canada Inc.	0.1	0.3
Alexion Pharmaceuticals Inc.[4]	0.0	0.0
Allergan Inc.	6.1	6.7
Amersham Health Inc. (GE Healthcare Inc.)	0.0	0.0
Amgen Canada Inc.[2,4]	6.8	7.8
Astellas Pharma Canada Inc.[2,4,7]	6.3	9.9
AstraZeneca Canada Inc.[2,4]	3.5	4.3
Axcan Pharma Inc.[2] (Aptalis Pharma Canada Inc.)	38.2	29.2
Bausch & Lomb Canada Inc.	0.0	0.0
Baxter Corporation[4]	0.3	0.4
Bayer Inc., Healthcare Division[2]	3.3	4.5
Biogen Idec Canada Inc.[4]	10.2	5.6
BioMarin Canada Inc.[4]	27.9	59.2
Biovitrum AB	0.0	0.0
Boehringer Ingelheim (Canada) Ltd.[2]	12.6	13.6
Bracco Diagnostics Canada Inc.	0.0	0.0
Bristol-Myers Squibb Pharmaceutical Group[2,4]	8.0	8.1
Celgene Canada[4]	2.9	6.3
Duchesnay Inc.	3.2	4.8
Eisai Limited [2,4,5]	0.0	—
Eli Lilly Canada Inc. (includes Provel Animal Health Division)[2,4]	11.1	10.7
EMD Serono Canada Inc.[2]	9.7	15.3
Ferring Inc.	1.0	3.8
Fresenius Kabi Canada	0.4	0.5
Fresenius Medical Care Canada	0.0	0.0
Galderma Canada Inc.	0.0	0.1
Genzyme Canada Inc.[4]	1.3	0.5
Gilead Sciences Inc.[2,4]	19.8	28.1
GlaxoSmithKline Inc.[2]	10.6	11.1
Graceway Pharmaceuticals (Medicis Canada Ltd.)	0.0	0.0
Hoffmann-La Roche Ltd. Canada[2]	3.7	5.0
Hospira Healthcare Corp.	0.0	0.0
INO Therapeutics[2]	0.0	0.0
Iroko International LP	0.0	0.0
Janssen Inc.[2,4]	5.1	7.5
Johnson & Johnson Merck, Consumer Pharmaceuticals of Canada	0.0	0.0
Johnson & Johnson Inc.	0.0	0.0
Johnson & Johnson Medical Products[5]	0.0	—
Lantheus MI Canada Inc.	0.0	0.0
LEO Pharma Inc.[2]	1.8	0.7
Lundbeck Canada Inc.[2]	0.6	1.6
Lundbeck Inc. (Ovation Pharmaceuticals Inc.)	0.0	0.0
McNeil Consumer Healthcare Canada	2.6	2.4
Merck Canada Inc.[2,4]	1.7	10.3
Merz Pharma Canada Ltd.	19.6	20.5
Novartis Consumer Health Canada Inc.	0.0	0.0
Novartis Pharmaceuticals Canada Inc.[2,4]	11.4	12.8
Novo Nordisk Canada Inc.[4]	2.2	2.1
Nycomed Canada Inc.[3]	0.0	0.5
Otsuka America Pharmaceutical[2]	0.0	0.0
Paladin Laboratories Inc.[2]	0.2	0.4
Pfizer Canada Inc.[2,4]	7.6	5.1
Pharmascience Inc.	7.4	8.8
Purdue Pharma[2]	2.0	2.3
Ranbaxy Pharmaceuticals Canada Inc.	0.0	0.0
Rare Disease Therapeutics Inc.	0.0	0.0
sanofi pasteur Ltd.[2,4,8]	46.0	48.9
sanofi-aventis Pharma Inc.[2,4,9]	8.2	8.2
Santhera Pharmaceuticals Canada Inc.[4]	2.5	2.9
Sunovion (Sepracor Pharmaceuticals Canada Inc.)[2]	0.01	0.03
Servier Canada Inc.[2]	3.8	7.5
Shire Canada Inc.[2]	0.2	0.0
Shire Human Genetic Therapies[4]	1.7	2.5
Sigma Tau Pharmaceuticals Inc.	0.0	0.0
Sopherion Therapeutics Canada Inc.	0.0	0.0
Takeda Canada Inc.[2,4]	5.9	3.5

Company	R&D-to-sales ratio (%)	
	2011	2010
Talecris Biotherapeutics Ltd.[4] (Grifols Canada Ltd)	0.9	0.9
Teva Canada Ltd. (Ratiopharm)	0.0	1.2
Teva Canada Innovation GP[4]	7.4	12.1
Theramed Corp.	0.0	0.0
Triton Pharma Inc.	0.0	0.0
Tyco Healthcare Group Canada Inc.	0.0	0.0
UCB Pharma Canada Inc.[4]	12.3	10.1
Unither Biotech Inc.	0.0	0.0
Valeant Canada Ltd.[4,6]	0.0	2.2
Warner Chilcott Canada Inc.[3]	0.3	0.4
YM Biosciences Inc.[2,4]	6843.6	5277.6

Notes:

1. To avoid double counting of sales revenues, revenues from royalties are included in calculating each company's ratio but not included in calculating industry-wide ratios. Federal and provincial government grants are subtracted from the R&D expenditure in calculating individual R&D-to-sales ratios but are included in calculating industry-wide ratios. Differences between the list of firms filing data on prices and those filing R&D data are due to differences in reporting practices of patentees and their affiliates or licensees. Note as well that some veterinary patentees (i.e., those without revenue from sales of products for human use) are required to file information on R&D expenditure but not price and sales information.
2. Member of RxR&D.
3. Formerly known as Aldara Pharma Inc. (prev. IFM Canada Inc.)
4. Member of BIOTECanada.
5. Not a patentee in 2010.
6. Formerly known as ICN Canada Ltd.
7. Formerly known as Fujisawa Canada Inc.
8. Formerly known as Aventis Pasteur Ltd.
9. Formerly known as Aventis Pharma Inc.

TABLE 23 Current R&D Expenditures by Province/Territory, 2011

Province	Expenditures: All patentees ($000)	Regional share (%)	Expenditures: R&D ($000)	Regional share (%)
Newfoundland	4,905.3	0.513	4,109.7	0.473
Prince Edward Island	111.4	0.012	111.4	0.013
Nova Scotia	10,932.4	1.144	10,114.4	1.164
New Brunswick	1,996.3	0.209	1,639.8	0.189
Quebec	411,777.2	43.104	373,586.3	43.013
Ontario	403,033.3	42.186	368,744.8	42.453
Manitoba	10,599.3	1.109	8,640.8	0.995
Saskatchewan	2,795.1	0.293	2,351.8	0.271
Alberta	65,756.9	6.883	62,294.3	7.172
British Columbia	43,347.7	4.537	36,893.1	4.247
Territories	59.5	0.006	59.5	0.006
Canada	955,314.4	100.0*	868,545.9	100.0*

* Values in this column may not add to 100.0 due to rounding.

Source: PMPRB

TABLE 24 Current R&D Expenditures by Performer and Province/Territory, 2011

Province		Patentees	Other companies	University	Hospitals	Others
Newfoundland	$000	636.9	1,597.2	799.3	355.2	1,516.7
	%	13.0	32.6	16.3	7.2	30.9
Prince Edward Island	$000	0.0	20.3	0.0	82.6	8.5
	%	0.0	18.2	0.0	74.2	7.6
Nova Scotia	$000	1,677.4	2,424.7	3,159.4	1,836.3	1,834.6
	%	15.3	22.2	28.9	16.8	16.8
New Brunswick	$000	214.7	848.2	0.0	417.3	516.0
	%	10.8	42.5	0.0	20.9	25.9
Quebec	$000	247,717.1	82,325.9	8,830.5	25,163.2	47,740.8
	%	60.2	20.0	2.1	6.1	11.6
Ontario	$000	186,683.8	83,423.9	24,750.9	62,901.6	45,273.2
	%	46.3	20.7	6.1	15.6	11.2
Manitoba	$000	2,224.3	3,181.6	1,417.1	2,632.4	1,143.9
	%	21.0	30.0	13.4	24.8	10.8
Saskatchewan	$000	396.2	982.2	802.5	245.6	368.7
	%	14.2	35.1	28.7	8.8	13.2
Alberta	$000	42,667.2	7,804.4	3,781.6	5,696.2	5,807.6
	%	64.9	11.9	5.8	8.7	8.8
British Columbia	$000	13,817.3	14,263.0	1,450.3	7,390.2	6,426.9
	%	31.9	32.9	3.3	17.1	14.9
Territories	$000	59.5	0.0	0.0	0.0	0.0
	%	100.0	0.0	0.0	0.0	0.0
Canada	$000	496,094.5	196,871.3	44,991.6	106,720.5	110,636.9
	%	51.9	20.6	4.7	11.2	11.6

Notes:

- The percentage under each R&D category gives the percentage of all money spent in that category in that province/territory.
- Expenditures as a percentage of total means percentage of R&D expenditures in that province compared to total R&D in Canada.
- Rows and columns may not equal totals due to rounding.
- Current expenditures plus capital expenditures (equipment + depreciation) = total R&D expenditures.

Source: PMPRB